



Han Kun Newsletter

Issue 225 (1st edition of 2026)

Legal Updates

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1. Key Takeaways from the Implementation Regulations of the Drug Administration Law (2026)

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The current Implementation Regulations of the Drug Administration Law was first enacted in 2002 (the “**2002 Regulations**”), with minor amendments made in 2016, 2019, and 2024. Following the release of a draft for public comment in 2022 (the “**2022 Draft**”), which could refer to our article: [《汉坤·观点 | 《药品管理法实施条例》\(修订草案\)重点快评》](#). Since 2002, the Regulations have now been comprehensively revised for the first time. The newly finalized version (the “**2026 Regulations**”) is set to take effect on May 15, 2026.

The 2026 Regulations systematically integrates over two decades of regulatory practice with the core principles of the Drug Administration Law. By providing a clear legal basis for several key regulatory mechanisms, the 2026 Regulations aims to establish a more robust and stable institutional framework for the rapidly evolving pharmaceutical industry. This article outlines and analyzes the key highlights of the 2026 Regulations, comparing them against the 2002 version and the 2022 Draft to help companies navigate the new regulatory landscape and understand its practical implications.

Offshore R&D activities

At the level of administrative regulations, the 2026 Regulations further consolidates the regulatory pathway for using overseas clinical trial data for domestic registration, reaffirming the core principle of “acceptable if compliant”. Specifically, the 2026 Regulations stipulate that drug development activities conducted overseas for the purpose of drug registration in China must comply with the Drug Administration Law, the 2026 Regulations, and all relevant national standards and specifications. This aligns with the 2022 Draft regarding the use of data generated from Multiregional Clinical Trials (“**MRCTs**”) for drug marketing authorization applications, and it effectively extends China’s regulatory requirements to offshore R&D activities intended for the China market. This also implies that MRCTs conducted outside of China must also be in compliance with China’s regulatory requirements. This underscores the National Medical Products Administration’s (“**NMPA**”) commitment to ensuring drug safety and strengthening oversight as pharmaceutical R&D becomes increasingly globalized.

The 2026 Regulations stipulate that research data obtained overseas may be used for drug registration applications in China, provided that such data meets the relevant requirements of the NMPA. This principle dates back to October 2017, when the General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation in Drugs and Medical Devices (commonly known as “**Document No.42**”), which first proposed the acceptance of foreign clinical trial data for domestic registration. In July 2018, the Center for Drug Evaluation (“**CDE**”) released specific technical guidelines

¹ Jingjing Xu and Yixi Zhao have contributions to this article.

to facilitate this process. The 2026 Regulations provides a stronger legal foundation for the acceptance of overseas data, thereby enabling the integration of global R&D resources and accelerating the development and market entry of innovative drugs.

The change of sponsor during IND phase

The 2022 Draft introduced, for the first time at the administrative regulation level, the possibility of changing the sponsor during clinical trials. It stipulated that such a change must be subject to the approval of the NMPA, although it did not provide detailed procedural requirements for the application process.

The 2026 Regulations reconfirms the principle that a change of sponsor must be approved by the NMPA, maintaining consistency with the 2022 Draft. This not only provides a clear legal basis for changing sponsors during a clinical trial but also implies that regulatory authorities may conduct a review to ensure the succeeding sponsor meets all necessary requirements. Such scrutiny may focus on the new sponsor's GCP compliance and its capacity to fulfill key obligations, including subject protection, investigational drug management, clinical trial data management, and risk management.

However, the specific pathway for changing a sponsor as a standalone application during a clinical trial remains in need of further clarification. This has long been a focal point of industry concern. Currently, Article 4 of the Guidelines for the Acceptance and Review of Changes to Chemical Drugs (Trial) (2021) suggests that a change of sponsor could be submitted alongside other supplemental application items. Beyond this, however, the procedural route for an independent sponsor change remains opaque. We hope that the implementation of the 2026 Regulations and subsequent detailed rules will bring greater flexibility to the Marketing Authorization Holder ("MAH") system.

Change of IND sponsor to a different NDA applicant

The 2022 Draft explicitly allowed the New Drug Application ("NDA") applicant and the Investigational New Drug ("IND") sponsor to be different entities. However, this specific provision was not retained in the 2026 Regulations. Despite its omission, it remains common in practice for the NDA applicant and IND sponsor to differ. This flexible arrangement has historically facilitated licensing transactions for products that are still in the clinical development stage.

Our practical experience indicates that companies must engage in detailed consultations with regulatory authorities prior to the NDA submission to confirm both the feasibility of a change in applicant and the specific procedural steps involved. Generally, applicants are required to submit explanatory materials characterized by clear logic and complete evidence to fully demonstrate compliance throughout the entire process of transitioning from the clinical trial sponsor to a different entity as the NDA applicant. Furthermore, given the absence of explicit regulatory provisions, we strongly recommend maintaining close communication with the CDE to seek formal confirmation in practice.

Market exclusivity

As widely anticipated, the 2026 Regulations formally introduces a Market Exclusivity for orphan drugs and pediatric drugs for the first time in China. Specifically, it grants a protection period of up to seven (7) years

for orphan drugs and up to two (2) years for pediatric drugs. During this exclusivity period, the NMPA will not approve the marketing of any identical drug products. Compared to the 2022 Draft, the 2026 Regulations have removed the provisions regarding first generic exclusivity. However, it is our understanding that the first generic exclusivity system was already established by the Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial) issued in 2021. Since the issuance of these Measures, pharmaceutical enterprises have successfully obtained 12-month first generic exclusivity periods. Following the established exclusivity system for generic drugs, this marks the official establishment of China's market exclusivity regime for orphan drugs and pediatric drugs.

The introduction of a market exclusivity regime is expected to provide sustained commercial protection for eligible products in China, creating a powerful incentive for the R&D and launch of orphan and pediatric drugs. Under the 2026 Regulations, the NMPA is slated to release follow-up implementation documents. We will continue to monitor these developments, with a focus on how the upcoming detailed rules will clarify operational essentials – including eligibility criteria, the specific scope of applicable drugs, the methodology for calculating protection periods and the concrete procedures for the NMPA to safeguard such exclusivity.

Regulatory data protection

The 2026 Regulations stipulate that China will provide a protection period of up to six (6) years for undisclosed trial data and other data independently obtained and submitted by MAHs for drugs containing new chemical entities and other eligible products. During this period, no other applicants may rely on such data to apply for drug registration without the consent of the MAH. This is commonly referred to as the Regulatory Data Protection (“RDP”).

China first introduced the principle of the RDP in the 2002 Regulations, yet detailed operational rules remained absent for many years. In 2018, the NMPA released the Implementation Measures for Drug Trial Data Protection (Interim) (Draft for Comments), which stipulated several detailed rules for the implementation of the Regulatory Data Protection (RDP) system; however, these measures never officially took effect. It was not until March 19, 2025, that the NMPA once again released the new Implementation Measures for Drug Trial Data Protection (Trial, Draft for Comment) and the Working Procedures for Drug Trial Data Protection (Draft for Comment) (collectively referred to as the “RDP Drafts”), providing guidelines for the RDP (please refer to our previous article: [Analysis of China's New Draft of Drug Regulatory Data Protection Rule \(Bilingual\)](#)).

We note that the phrasing regarding the scope of drug protection in the 2026 Regulations is highly similar to that in the RDP Drafts. This suggests that the new RDP regime's scope may be interpreted in alignment with those drafts: potentially extending beyond innovative drugs to include improved new drugs and first generics, among others. With the finalized Regulations now in place, we look forward to the early promulgation and implementation of the supporting rules for RDP, which is of great concern to the industry. Such progress will enable the system to fully realize its functions of incentivizing innovation and facilitating transactions.

Commercial sale of validation batches produced prior to regulatory approval

Driven by capacity and market considerations, the commercial sale of validation batches produced prior to regulatory approval is a major focus for the industry, and a frequent inquiry we receive from clients. Historically, industry understanding of this issue has relied primarily on Article 52 of the Measures for the Supervision and Administration of Drug Manufacture (2020), the NMPA Announcement on the Import of Commercial-Scale Batches of Drugs Marketed Overseas Prior to Domestic Approval (2025), and various provincial guidelines. However, enforcement standards have varied significantly across different regions.

The 2026 Regulations explicitly stipulate that commercial-scale batches manufactured prior to obtaining drug registration approval – and which have passed the corresponding Good Manufacturing Practice (“GMP”) compliance inspection – may be marketed and sold after approval is granted, provided they meet all drug release requirements. Furthermore, for new drugs, orphan drugs, drugs in short supply, and other clinically urgently needed drugs, commercial-scale batches produced after passing the relevant GMP compliance inspection are also eligible for commercial sale.

Overall, the regulatory policy supports the commercial sale of designated products (including both domestic and imported drugs) manufactured prior to approval, with the aim of fostering innovation and securing market supply. However, based on our practical experience, provincial-level drug regulatory authorities have long maintained divergent approaches to enforcement. With the new Regulations now finalized, it remains to be seen how local authorities will interpret and implement these provisions in practice.

Segmented production of drugs

The Drug Administration Law does not prohibit the segmented production of drugs. Article 69 of the 2022 Draft for the first time proposed that innovative or clinically urgently needed drugs with special requirements may be manufactured in segments, subject to approval. Specifically, the Provisions on the Supervision and Administration of Vaccine Production and Distribution (2022) also clarified that the production of vaccine drug substance (bulk) and drug product (finished dosage form) may be outsourced separately upon the NMPA’s consent.

The 2026 Regulations formally establish the legal and operational framework for segmented drug production at the level of administrative regulations. Subject to the prerequisite of “demonstrated necessity”, this provision limits the application of segmented production to specific types of drug products and emphasizes that it must be implemented under the unified responsibility of the MAH, subject to approval by regulatory authorities. This arrangement reflects the regulators’ approach of providing operational flexibility for production organization while strictly adhering to the principle of the MAH’s comprehensive liability.

Regarding the scope of application, Article 32 of the 2026 Regulations not only covers innovative drugs with special requirements for production processes or facilities and equipment, but also explicitly includes clinically urgently needed drugs, drugs for responding to public health emergencies, and stockpile drugs. Furthermore, it provides a catch-all provision for “other drugs as stipulated by the drug supervision and administration department under the State Council”, thereby leaving room for future institutional expansion.

By comparison, Article 32 of the 2026 Regulations largely retains the provisions on segmented production from the 2022 Draft, stipulating that entrusted segmented production may be implemented for the aforementioned drug categories provided that the relevant requirements are met. Simultaneously, it incorporates the content regarding the segmented production of vaccines from the Provisions on the Supervision and Administration of Vaccine Production and Distribution (2022). It is stipulated that under specific circumstances where the production capacity of a Vaccine MAH is exceeded, the Vaccine MAH may, upon approval, entrust qualified vaccine manufacturers with the production or segmented production of vaccines. This provision thereby providing a higher-level legal basis for those specific vaccine regulations.

It is worth noting that a Pilot Program for the Segmented Production of Biological Products was introduced in 2024 (see our previous article: [Key Takeaways on China's Pilot Plan for Segmented Production of Biological Products \(Bilingual\)](#)). This program has already been implemented in several pilot cities. However, the 2026 Regulations do not specifically single out the segmented production of biological products. With a clear higher-level legal basis now in place, we anticipate more practical applications of segmented production for biologics. In August 2025, the State Council approved the Plan for Promoting the Open Innovation and Development of the Entire Bio-pharmaceutical Industry Chain in the China (Jiangsu) Pilot Free Trade Zone. The Plan explicitly encourages the China (Jiangsu) Pilot Free Trade Zone to explore and launch pilot programs for the segmented production of chemical active pharmaceutical ingredients (“APIs”) and biological products. We have noted that the 2026 Regulations do not restrict segmented production to biological products. This omission suggests that the current revision may have reserved legal space in a superior law level for the further advancement of segmented production for chemical drugs in the future.

Online drug transactions responsibilities

The 2026 Regulations formalize and further update the provisions on online drug transactions from the 2022 Draft. They mandate that third-party platforms fulfill their quality management responsibilities, which include verifying the qualifications of the operating entities on the platform. Furthermore, the Regulations provide detailed requirements for information disclosure and hyperlink redirection for all parties involved in online drug transactions.

According to the 2026 Regulations, if a third-party platform fails to establish a compliant online drug sales quality management system, or if an online drug transaction entity (including third-party platforms, MAHs, and drug distributors) provides information disclosure or hyperlink redirection services to other third parties (e.g., displaying drug information for other enterprises or redirecting clicks to external drug purchase pages) in violation of drug supervision regulations, they shall be subject to administrative penalties. These penalties include orders for rectification, confiscation of illegal gains, or fines ranging from RMB 100,000 to RMB 2,000,000, depending on the severity of the circumstances. This update reflects the regulatory initiative to enforce the primary responsibilities of online drug transaction platforms and merchants while strengthening internal platform management.

It is evident that as online drug transaction activities evolve, the internet has become a critical channel for the public to access medicines. Consequently, the responsibilities of all parties involved are being

progressively codified under drug supervision regulations, while key conduct issues in online transactions are now explicitly addressed at the legislative level.

Priority review and approval of drugs

China's reform of the drug review and approval system to encourage innovation has a long history. As early as 2015 and 2017, the State Council proposed accelerating the review of innovative drugs in the Opinions on Regulating the Review and Approval System for Drugs and Medical Devices (2015) and Document No.42 (2017), which required the implementation of conditional approval and priority review and approval for clinically urgently needed drugs. Guided by these top-level designs, the NMPA released several guiding documents concerning priority review and approval.

The Provisions for Drug Registration (2020) marked the first time that the four (4) accelerated approval pathways – namely, Breakthrough Therapy Designation, Conditional Approval, Priority Review and Approval, and the Special Approval Procedure – were systematically integrated into a unified departmental regulation with detailed implementation rules. The 2026 Regulations sustain this framework and ultimately elevate these four (4) accelerated pathways to the level of administrative regulations, providing them with a solid superior law basis.

In China, a multi-channel framework for encouraging drug market entry is gradually taking shape. This includes the integration of a series of new pilot regulations for drugs and medical devices in Hainan, along with the implementation of the Regulations on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies (2025), enterprises can now achieve technological transformation and application through the “New Biomedical Technology” pathway, ultimately benefiting a broader patient population (See our article: [《汉坤·观点 | 海南博鳌乐城临床急需进口药械管理新规亮点评析》](#) and [Key Takeaways on China's Regulations on the Clinical Study and Clinical Translation and Application of New Biomedical Technologies – A New Era for IITs and Commercialization in Cell and Gene Therapy \(Bilingual\)](#)).

Bundled review and approval system for active pharmaceutical ingredients

Since the issuance of the Measures for the Administration of Drug Registration (2020), China has fully implemented the bundled review and approval system for APIs. Under this system, a Notice of Approval is issued for chemical APIs that have passed the bundled review alongside the finished drug product. Notably, the 2026 Regulations stipulate the issuance of a Certificate of Approval for Chemical APIs, upgrading the terminology from “Notice” to “Certificate”. This change formally enhances the authority of the credential. Meanwhile, the 2026 Regulations further clarify and support the transfer of the API certificate, providing a clearer and more solid institutional foundation for the circulation and transaction of rights related to APIs.

Our understanding is that the 2026 Regulations do not alter China's existing bundled review and approval system for APIs. The provision allowing for the transfer of the Certificate of Approval for Chemical APIs aligns with the policy direction of “optimizing API management and lawfully changing API registration entities”, as proposed in the Opinions of the General Office of the State Council on Comprehensively

Deepening the Reform of Drug and Medical Device Supervision to Promote High-Quality Development of the Pharmaceutical Industry ([2024] No. 53). Given the current lack of detailed implementation measures, the specific operational path for such transfers remains to be clarified by subsequent supporting rules and warrants continuous attention.

Conversion mechanism between prescription drugs and over-the-counter drugs

China's drug regulatory system, centered on the Drug Administration Law, has long implemented the classified management of prescription drugs and over-the-counter ("OTC") drugs; however, a formal mechanism for the conversion between these two (2) categories has long lacked a higher-level legal basis. Both the 2022 Draft and the 2026 Regulations introduce a standardized conversion system, stipulating that the MAH may apply to switch a prescription drug to OTC status, or convert a registered prescription drug to an OTC drug. Conversely, the NMPA is also empowered to convert an OTC drug back to prescription-only status following an official evaluation to ensure public medication safety.

In fact, the CDE has previously issued the Guiding Principles for the Scope of Applications to Switch Prescription Drugs to OTC Status and the Data Requirements for Prescription-to-OTC Conversion Applications, providing detailed operational guidance for the switch mechanism. The newly introduced provisions in the 2026 Regulations now further provide a higher-level legal basis for these rules. Under this framework, "old drugs" that have reached patent expiry or are facing fierce market competition may be able to extend their product lifecycles by switching to the OTC market.

MAH domestic responsible persons

In practice, many of our overseas clients are highly concerned about the qualification requirements for domestic responsible persons in China. Overall, relevant regulatory requirements are continuously increasing, and the compliance capability requirements for domestic responsible persons are gradually converging with the standards applicable to MAHs themselves across multiple dimensions.

While the Drug Administration Law establishes the principle that domestic responsible persons shall bear joint and several liability, Article 25 of the 2026 Regulations significantly extends this requirement. It explicitly stipulate that the domestic MAH agent designated by an overseas MAH must possess corresponding "quality management capabilities" and "risk control capabilities", and must establish dedicated management departments staffed with appropriate personnel. This provision mirrors the high standards set forth in Articles 23 and 24 of the 2026 Regulations regarding the quality assurance and pharmacovigilance systems required for MAHs themselves. Consequently, a domestic MAH agent that lacks a supporting quality and risk control system will find it difficult to meet the qualification requirements under the new regulatory regime.

Meanwhile, the 2026 Regulations echo Article 7 of the Provisional Administrative Measures for the Designation of Domestic Responsible Persons by Overseas Marketing Authorization Holders (Announcement No.137, 2024), adding a new requirement that "the relevant information of the designated domestic legal entity must be stated in the drug package insert". (For more information regarding Announcement No.137, please refer to our article: [*Strengthening Oversight of Imported Drugs: Key*](#)

Takeaways into New Regulations on Domestic Responsible Entities (Bilingual) This provision means that domestic responsible persons will not only be subject to regulatory inspections but will also directly face patients and the public, further strengthening their legal status as the responsible entities within China. Therefore, we recommend that when searching for and designating a domestic MAH agent, overseas enterprises should focus on auditing the agent's qualifications and capabilities to ensure that they possess a compliance system capable of substantively undertaking statutory responsibilities.

Accessible drug labels and package inserts

Article 26 of the 2026 Regulations explicitly introduces accessibility requirements for drug labels and package inserts for the first time. Compared to the 2002 Regulations and the 2022 Draft, the new rules formally mandate that MAHs must provide accessible formats – such as audio, large print, Braille, or electronic versions – to ensure safe medication use for persons with disabilities and the elderly. Given their nature as technical aids in practice, audio and Braille versions of drug labels and package inserts are currently positioned as being “for reference only”.

The implementation of this system demonstrates that China's drug regulation, while pursuing rigor, is increasingly focusing on the practical needs and medication rights of vulnerable groups. Furthermore, it represents a concrete fulfillment of the national “age-friendly” transformation policy within the pharmaceutical sector.

Importation of clinically urgently needed drugs and small quantities of drugs for personal self-use

The Drug Administration Law stipulates that medical institutions may, for clinically urgently needed reasons, import small quantities of drugs upon approval by the NMPA or its authorized departments, provided they are used for specific medical purposes within designated institutions. On the basis of reaffirming this system, the 2026 Regulations introduce a new requirement to consult the National Health Commission (“NHC”) for its opinion. We understand that since such medication demands originate from medical institutions and are used internally, it is reasonable to incorporate the NHC into this regulatory synergy. In practice, the import of clinically urgently needed drugs may be carried out with reference to the Work Plan for the Temporary Import of Clinically Urgently Needed Drugs, jointly issued by the NHC and NMPA in June 2022.

Compared to the 2002 Regulations, the 2026 Regulations introduce new provisions stipulating that the personal carrying or mailing of small quantities of drugs into China shall be limited to reasonable quantities for self-use and must comply with national regulations governing the entry of personal effects. This requirement generally maintains the regulatory approach of the 2022 Draft. The author believes that under the current policy framework, there remains a certain degree of policy leeway for cross-border e-commerce platforms to conduct retail drug import business. However, the compliance boundaries and regulatory interpretations in this area warrant continuous attention to policy trends and the evolution of enforcement practices.

Counterfeit and substandard drugs

Cracking down on counterfeit drugs has consistently been a focal point of China's drug regulation. In recent years, relevant systems have been continuously refined at both the administrative enforcement and criminal liability levels. Based on our practical experience, issues surrounding counterfeit and substandard drugs in the distribution sector – along with their impact on medication safety, market order, and brand reputation – remain high-priority risk areas for pharmaceutical enterprises.

While maintaining the basic framework of Article 98 of the Drug Administration Law, the 2026 Regulations provide further granularity regarding the determination of counterfeit drugs. It explicitly lists several typical scenarios, including but not limited to, drugs labeled with fraudulent drug approval numbers or false MAH information.

Notably, the 2026 Regulations further clarify that under specific circumstances, relevant products may be determined to be counterfeit or substandard drugs directly without undergoing laboratory testing. Examples include cases where a drug has clearly deteriorated, or where evidence such as procurement and usage records can sufficiently prove its status as counterfeit or substandard. These provisions will significantly enhance enforcement efficiency and strengthen the capacity for the rapid disposal of such drugs. This also reflects the regulatory authorities' determination to maintain a strict crackdown on counterfeit drugs and to purify the pharmaceutical market order.

Statutory time limits for administrative approval

The Measures for the Administration of Drug Registration (2020) and the Measures for the Administration of GLP Certification for Non-clinical Laboratory Studies (2023), in their provisions regarding the working timelines for drug registration, and the review of laboratory qualification applications, have already excluded the time required for supplementing data, providing feedback, implementing rectifications, and conducting overseas inspections from the administrative timelines. Similarly, the Measures for the Supervision and Administration of Drug Manufacture (2020), the Measures for the Supervision and Administration of Drug Marketing and Use (2024), and the NMPA Announcement on Strengthening the Supervision of Contract Manufacturing by MAHs (2023) explicitly exclude technical review time from their respective application timelines. Nevertheless, these provisions on working timelines are currently scattered across various levels of departmental rules and normative documents, leading to a lack of systemic cohesion.

For the first time at the administrative regulation level, the 2026 Regulations stipulate that the time required for technical review involved in applications for drug registration, GLP laboratory qualifications, drug manufacturing licenses, drug distribution licenses, and medical institution preparation licenses, shall not be counted towards the statutory time limits for administrative licensing. By consolidating previously scattered rules, the Regulations provide applicants with clearer legal expectations regarding review and approval timelines, while simultaneously ensuring that regulatory authorities have the necessary time to conduct rigorous technical evaluations.

Importation of investigational medicinal products, comparator drugs and samples required for research or testing for registration purposes

Compared to the 2022 Draft, the 2026 Regulations introduce new provisions governing the import of investigational medicinal products (“**IMPs**”), as well as the import of comparator drugs and samples required for research or testing for registration purposes. Article 10 of the 2026 Regulations stipulates that the import of comparator drugs and samples for research or testing aimed at drug registration shall be subject to approval by the NMPA. Furthermore, drugs intended for clinical trials as specified in the Clinical Trial Approval (“**CTA**”) documents may be imported by presenting such approval documents.

Our understanding is that prior to the issuance of the CTA (i.e., the pre-IND stage), the import of comparator drugs and samples for testing or research (such as non-clinical studies) must be approved by the drug regulatory authorities. Once the IND is approved, IMPs – which, according to GCP regulations, include comparator drugs – as specified in the CTA documents may be imported by presenting said documents without the need for additional regulatory approval. However, if the drugs intended for use fall outside the scope of those specified in the CTA documents, a separate regulatory approval for import remains mandatory.

Legal liability

The 2002 Regulations contained relatively simplistic provisions on legal liability, primarily prescribing penalties in accordance with the Drug Administration Law (2019) without specifying concrete fine amounts. In contrast, the 2026 Regulations is far more detailed, providing explicit ranges and calculation methods for fines. Depending on the nature of the violation, penalties can now trigger a maximum fine of 5 million RMB. Furthermore, the 2026 Regulations have expanded the scope of punishable acts compared to the Drug Administration Law (2019). For instance, “providing false certificates, data, materials, or samples, or employing other deceptive means when applying for the qualification of non-clinical safety evaluation research institutions” has now been incorporated into the scope of administrative penalties. Additionally, it is stipulated that where false certificates are provided during the filing of a drug clinical trial institution, the relevant clinical trial data shall not be utilized in applications for drug registration. Overall, the 2026 Regulations demonstrate a much higher level of granularity.

Conclusion

Overall, the 2026 Regulations mark a new stage of maturity for China’s drug regulatory system. Building on the achievements of the MAH system and reforms in the review and approval process, the 2026 Regulations demonstrate a forward-looking and sophisticated approach by actively addressing industry concerns such as market exclusivity, data protection, fragmented production, importation of clinically urgently needed drugs and online drug sales. Naturally, the operational details of certain provisions still require further clarification through supporting rules. We look forward to the prompt issuance of relevant guidelines by regulatory authorities to ensure smooth and effective implementation that fully unlocks the potential of these new policies. Moving forward, we will continue to monitor all developments closely to provide our clients with timely and expert legal support.

2. Safeguarding Overseas Assets: the Strategic Necessity of Pre-Investment Treaty Structuring for Chinese Outbound Investors

This article was jointly authored by Wei (Vincent) Sun, Yuxian Zhao, Long Liu, Yanlong Li, and Shuyu Wei from Han Kun Law Offices, together with Professor Robert Volterra and Haoyu Rao from Volterra Fietta²

Introduction

As China's outbound investment footprint expands across infrastructure, energy, mining, technology, and real estate, Chinese companies are increasingly navigating complex political, regulatory, and commercial landscapes. While commercial contracts – such as joint-venture agreements – are fundamental, they often provide limited protection when the interference comes from the host State itself. This is particularly the case where the host State interferes with the investment but is not itself a party to the commercial contracts (for example, by refusing to renew licenses or by imposing sanctions or economic activity restrictions based on nationality). Real-life examples of such interference against Chinese investors can be seen happening recently in Europe, the Americas, Australia and Africa.

In scenarios where domestic remedies are ineffective, procedurally biased, or susceptible to political influence, a critical question arises: **how can Chinese companies investing overseas secure their assets against sovereign interference under international law?**

This article introduces a vital yet often unknown or overlooked tool: **Bilateral Investment Treaty (BIT) structuring**. Such treaties, signed between governments and provide benefits to businesses making investments between those countries. By establishing an ownership structure of their foreign investment that is optimised to get them such treaty protection, Chinese companies can ensure they have recourse to international law and arbitration against an interfering host State, when facing State-level disputes.

However, a common misconception persists among Chinese investors. Many assume that BIT planning is only relevant if China has a direct treaty with the destination country, or worse, that structuring can be arranged *after* problems arise. This is not true. Chinese companies can set up subsidiaries in other countries that then let them have BIT protection against the host country of their investment, even when China does not have a BIT (or not the best one). These misconceptions have led to costly outcomes, including deadlocked domestic litigation, unenforceable arbitration awards, and multimillion-dollar losses.

Through two case studies, this article outlines practical strategies for leveraging public international law to protect overseas investments.

Two cases for understanding the catastrophic consequences of the lack of pre-investment structuring under public international law

- **Case A: without treaty protection, investors may bear losses with no recourse**

² Yixin Yuan has contributions to this article.

In the mid-2000s, a Chinese company entered into a joint development project with a foreign State's local government entity to build a commercial complex in a prime urban district. Although the project initially received approvals from various governmental authorities, the planning landscape changed repeatedly over the following years. Different government bodies issued conflicting directives. Some permitting the project to continue, others suspending or relocating it due to newly prioritised public infrastructure works and urban redevelopment plans. Despite the Chinese company's continuous efforts to revise and resubmit construction plans in line with shifting regulatory requirements, key local agencies ultimately refused to authorise construction on the grounds of public-safety risks. During this period, the foreign State dissolved the local governmental entity that had been the Chinese company's joint-venture partner. The foreign State denied any legal succession to the original contract. Domestic courts rejected the Chinese company's claims to compel administrative approval and refused to designate a successor for the dissolved governmental entity. The Chinese company has no other recourse to request compensation but to enter into endless and hopeless negotiation with this foreign State.

Here, this foreign State does not have a BIT with China, and this Chinese company did not structure its investment to a country having a BIT with this foreign State. After the dispute arose, it is too late for international protection to attach since the international investment arbitration tribunal will reject jurisdiction if the structure happens after the dispute with the foreign State becoming foreseeable³. The Chinese company was therefore forced to rely exclusively on domestic proceedings, where state-affiliated authorities declined to provide relief. After exhausting all available domestic remedies, the Chinese company had no remaining pathway to hold the host State accountable at the international level. As a result, the project collapsed, and the Chinese company suffered losses of approximately USD 100 million.

■ **Case B: the “pyrrhic victory,” winning without effective monetary recovery**

A Chinese company entered a major overseas mining project through a joint venture with a locally incorporated company. Although this local company had been formed with strong political backing and enjoyed support from senior government officials, the foreign State itself never formally established or owned the local company. The joint venture was granted long-term rights to develop a large mineral deposit, with the Chinese company holding the majority shares. Over time, however, the local partner repeatedly failed to contribute the agreed financial commitments, and the foreign State did not grant the necessary licenses for conducting the mining.

Despite the Chinese company's efforts to stabilise the project, various government agencies began creating administrative obstacles: delaying approvals, citing environmental or community concerns as grounds to halt operations altogether. Some key ministries refused to issue necessary authorisations for mining or for the transfer of concession rights. With no BIT in force between China and the host

³ See *Philip Morris Asia Limited v. The Commonwealth of Australia*, UNCITRAL, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, 17 December 2015, paragraphs 533 – 534. See also *ST-AD GmbH v. Republic of Bulgaria*, UNCITRAL, PCA Case No. 2011-06, Award on Jurisdiction, 18 July 2013, paragraphs 421 – 423; *Pac Rim Cayman LLC v. Republic of El Salvador*, ICSID Case No. ARB/09/12, Decision on Respondent's Jurisdictional Objections, 1 June 2012, paragraph 2.99.

State, the Chinese company lacked any international treaty-based avenue to hold the government accountable under international law.

When the dispute escalated, the Chinese company's only legal remedy was to invoke the commercial arbitration clause in its joint-venture contract and initiate proceedings against the local partner at an international commercial arbitration institution. Even if the Chinese company were to win such an arbitration, this victory would be largely symbolic: the local partner had limited assets and was financially incapable of satisfying an award. Because the company was privately incorporated and not legally owned or controlled by the State, the Chinese company had no chance to pierce the corporate veil to enforce the award against the government itself. With no treaty protection, no basis for State responsibility, and no jurisdiction before an international investment tribunal, the Chinese company would be unable to elevate the claim to the international level to secure actual compensation paid by the foreign State.

This scenario demonstrates a recurring structural risk: without taking into account the international law to have a proper pre-investment structure, even a favourable commercial arbitration award may amount to nothing more than an "empty win": legally valid on paper but unenforceable in real money in practice, leaving the Chinese company with significant sunk costs and no effective remedy.

Strategic planning: how to secure BIT protection

A BIT is an international agreement concluded between two sovereign States to promote and protect cross-border investments. Under a BIT, each State commits to safeguard the investments made in its territory ("host State") by investors from the other State ("home State")⁴. In doing so, BITs create binding obligations under public international law. These obligations are not merely political commitments or soft-law guidelines; rather, they constitute enforceable legal duties. When a host State breaches these duties by, for example, expropriation or other forms of interference, foreign investors can seek compensation or other remedies through international investment arbitration against the host State directly, without the need of having an arbitration clause signed with the host State.

Once an investor and its asset satisfy the definitions under a certain BIT, the protections of the BIT become fully applicable. This includes access to international investment arbitration, a neutral forum where investors can bring claims directly against the host State. This is something impossible under domestic law and commercial arbitration alone. It is precisely this feature that makes BIT structuring essential: without it, investors lack any treaty-based pathway to hold a foreign State accountable under international law.

For more details, please refer to our previous article: "*Hankun's Guide to Overseas Business: Treaty Protection and Investment Arbitration (I) – Overview* ([汉坤企业出海系列：条约保护及投资仲裁（一）——概览篇](#))".

⁴ See Marc Jacob, "Investments, Bilateral Treaties," *Max Planck Encyclopedia of Public International Law*, June 2014, accessed December 2, 2025, <https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1061>.

If the Chinese companies in the above two cases had used the BITs to structure their investment, what would be the different results

I. General strategy to get BIT protections

Contrary to popular belief, the absence of a BIT between China and the investment host State **does not necessarily** preclude Chinese companies from enjoying BIT protection. The key lies in **treaty structuring**: utilising a jurisdiction that *does* have a favourable BIT with the host State. Critical steps include:

- **Step 1: Comprehensive BIT Mapping:** identifying all BITs previously signed and ratified by the host State (the invested destination);
- **Step 2: Substantive Strength Analysis:** analysing the breadth and strength of substantive protections in each BIT;
- **Step 3: Procedural Access Evaluation:** evaluating procedural access to investor–State arbitration; and
- **Step 4: Broader Commercial Considerations:** considering broader factors such as tax efficiency, corporate governance and political risk.

II. How to apply the above strategy and how would the outcome differ

■ **Step 1: Comprehensive BIT Mapping**

The first step in BIT planning is to categorise all investment treaties that the host State has signed and ratified.

If this exercise had been carried out in Case A, the Chinese company would have discovered that although the host State had no BIT with China, it did maintain BITs with many jurisdictions commonly used for outbound investment structuring. Any of these jurisdictions have the potential to be a viable home for a treaty-protected holding company. A comprehensive BIT review would be able to show that Chinese company was not limited by China’s treaty network; rather, it could rely on the host State’s treaties with a third State. Similarly, in Case B, a BIT reviewing exercise would have revealed that the host State was party to BITs with jurisdictions offering stable legal systems, predictable corporate regulation, and access to strong treaty protections. In both cases, this first step alone would have opened the door to structuring options unavailable to the investors due to their decision to invest directly from China.

■ **Step 2: Substantive Strength Analysis**

The second step is to analyse comprehensively the relative strength of all the BITs identified in the first step and to shortlist at least ten BITs. Not all BITs are created equal.

For example, in Case A, the key risks the investor ultimately faced include dissolution of the joint-venture counterparty, refusal to designate a successor, contradictory governmental directives, and long-term deprivation of the project’s value, which requires a well-drafted BIT containing protections

addressing all the risks. A careful comparison of the host State's BITs would have shown that certain BITs contained broad definitions of expropriation and strong Fair and Equitable Treatment (FET) language protecting investors from arbitrary administrative conduct, while other BITs contain restricted definitions. If a BIT also included an umbrella clause elevating contractual commitments to treaty status, it would have provided far superior protection than other BITs that lacked such provisions. After finishing this step, at least ten BITs should be shortlisted.

■ **Step 3: Procedural Access Evaluation**

The third step is to evaluate the procedural access that each BIT provides.

Even the strongest substantive protections are ineffective if the BIT does not grant direct access to investor-State arbitration. For example, in Case A, the investor would have needed a treaty allowing immediate recourse to International Centre for Settlement of Investment Disputes ("ICSID") or United Nations Commission on International Trade Law ("UNCITRAL") arbitration without requiring lengthy domestic litigation or subjecting the investor to restrictive "fork-in-the-road" provisions. For example, if a BIT required an 18-month domestic litigation period before arbitration, while another BIT allowed the investor to bypass local courts and proceed directly to ICSID, the second BIT would have been procedurally superior. In Case B, procedural access was even more crucial. If one of the host State's BIT allowed arbitration for any alleged violation, whereas its BITs with another jurisdiction restricted arbitration to expropriation claims or the quantum only claims, the first BIT would have been the more effective and powerful choice. Through this procedural analysis, both companies should have ensured direct recourse against the host State rather than being trapped within domestic systems or limitations to their claims.

■ **Step 4: Broader Commercial Considerations**

The fourth step requires consideration of broader commercial and regulatory factors such as tax efficiency, corporate governance, and political risk. A holding company jurisdiction with favourable taxation arrangements could significantly reduce the overall tax burden of a long-term commercial project.

Again, it is important to emphasise that not all BITs are equal, and the choice of treaty cannot be made mechanically. Each BIT contains its own definitions of investment and investor, substantive protections, procedural pathways, and limitations. The effect of these differences can dramatically alter a Chinese company's rights. In practice, counsels specialising in international law must evaluate and rank potential treaties through a multi-factor analysis, including but not limited to: whether the BIT grants tribunals full jurisdiction over all treaty breaches (rather than limiting claims to quantum or certain issues only); whether the treaty expressly protects investments made before its entry into force; whether its expropriation, fair and equitable treatment, umbrella clause and other protections are well drafted to address the specific risks that Chinese company faces; and whether the proposed restructuring jurisdiction has credible, commercially rational reasons for use. It is a comprehensive work requiring professional service by international law lawyers.

In Case A and Case B, had these Chinese companies structured their investments through a

jurisdiction protected by a BIT with the host State, the results in both cases would have been fundamentally different. Instead of relying solely on domestic courts or unenforceable commercial awards, they would have been entitled to invoke the full suite of investment protections granted by international law and bring claims directly against the host State.

In Case A, if the Chinese company had structured its investment through a BIT-protected vehicle, the host State's dissolution of the joint-venture counterparty, refusal to designate a successor, and effective deprivation of the investment's value would constitute unlawful expropriation. The investor could claim compensation equivalent to the fair market value of the project, which is far beyond what domestic courts were prepared to recognise.

In Case B, had the Chinese company structured its investment through a BIT-protected jurisdiction, instead of suing a bankrupt local partner, the Chinese company could have brought a claim against the host State for its role in obstructing licenses. This would have transformed an unenforceable commercial award into a binding international award payable from the State's sovereign resources.

III. Timing is critical: Chinese companies investing overseas should restructure as soon as possible, ideally before a potential dispute with the host State has crystallised

BIT protection can be obtained through restructuring after an investment has been made. But it is only effective if the investment is structured before the dispute becomes foreseeable with high probability. As discussed above, international tribunals consistently reject jurisdiction where treaty structuring occurs after early indicators of conflict have already appeared.

In both Case A and Case B, by the time systemic obstacles emerged (including governmental refusal to issue approvals, dissolution of contractual counterparties, administrative blockages, and clear signs of State hostility) the disputes had already become foreseeable. Restructuring at that stage would have been considered an abuse of process, and any subsequent claim under a BIT would likely have been dismissed for lack of jurisdiction.

This is why proactive planning is indispensable. Chinese companies "going global" must adopt a proactive legal strategy. By establishing a treaty-protected structure at the outset – long before the first sign of trouble – investors secure a powerful shield that can make the difference between a total loss and a full recovery.

3. Analysis and Comparison of Key Terms in China NewCo and License-in/out Deals in 2025

Authors: Aaron GU | Cathy ZHENG | Matt ZHANG | Franky YU | Naifang ZHANG | Shuwen SUN | Krystal ZHAO | Lingyu SHENG⁵

License-in/out, Spin-off-NewCo model (commonly referred to as “SON” or “NewCo” model) , and other transaction models serve as critical strategic tools for pharmaceutical and medical device companies to generate revenue, advance pipeline research and development (“R&D”), and expand into global markets, maintaining strong momentum in 2025. According to relevant statistics, the total value of outbound business development (“BD”) deals for China’s innovative drugs reached USD 135.655 billion in 2025, with upfront payments amounting to approximately USD 7 billion. A total of 157⁶ transactions were recorded, nearly doubling both the value and volume compared to 2024, setting new historical records across all metrics. The Chinese innovative pharmaceutical industry continues its high-quality growth trajectory, with Chinese innovator companies emerging as significant drivers in the global life sciences and healthcare market. Against this backdrop, in addition to the ongoing active License-out deals, the NewCo model has emerged in recent years as an increasingly popular pathway for global expansion, enabling several Chinese biopharma companies to gain a first-mover advantage in global competition. (For practical insights and an in-depth analysis of the NewCo model and the SON strategy, please refer to our previously published articles [Six Key Insights into China Biotech’s NewCo Model](#) and [Insights into China Biotech’s New Approach: Spin-off-NewCo Model](#)). Furthermore, in July 2025, [Sino Biopharm completed the landmark full acquisition of LaNova Medicines](#), marking the first instance in China where a major domestic pharmaceutical company acquired a Biotech firm—an unprecedented transaction model with milestone significance. In this transaction, our team had the privilege of serving as legal counsel for Sino Biopharm, providing comprehensive legal services throughout the process.

Our team has been 100% dedicated to corporate, regulatory compliance, and transactional services for life sciences, biopharmaceutical, medical and healthcare industries, and has supported more than 100 transaction projects to date. In 2025, we also represented numerous renowned multinational pharmaceutical companies, leading Chinese innovative drug and biotechnology companies, and top domestic and international investment institutions in dozens of highly significant License-in/out and NewCo projects with substantial industry impact. Meanwhile, we have also observed that an increasing number of overseas Biotechs and investors are proactively turning their attention to China, conducting Investigator-Initiated Trials (“IITs”) in the country to obtain earlier and more valuable human data. This trend highlights, to some extent, China’s comprehensive strengths in clinical trial efficiency, subject resources, and execution capabilities, and reflects a growing global strategic emphasis on leveraging China for early-stage validation of project feasibility and mitigation of early R&D risks. (For the latest developments on IIT regulation, please refer to our previously published article [Key Takeaways on China’s Regulations on the Clinical Study and Clinical Translation and Application of New Biomedical Technologies - A New Era for IITs and Commercialization in Cell and Gene Therapy](#)).

⁵ Jingjing Xu and Yixi Zhao have contributions to this article.

⁶ Please refer to: <https://finance.sina.com.cn/stock/relnews/hk/2026-01-04/doc-inhfctqp2857071.shtml>.

In 2025, we continued to focus on the life sciences and healthcare sector, including a systematic analysis of the new draft regulation on drug regulatory data protection and the potential new opportunities it may bring to innovative drug transactions (please refer to: [Analysis of China's New Draft of Drug Regulatory Data Protection Rule: A New Perspective on Innovative Drug Transactions](#)), as well as an in-depth examination—combining extensive industry experience and cutting-edge insights—with the dispute resolution team of two critical contentious issues in License-in/out agreements (please refer to: [汉坤·观点 | 生命科学行业 License-in/out 合同争议要点分析\(四\): 首付款是否可能退回?](#) and [汉坤·观点 | 生命科学行业 License-in/out 合同争议要点分析\(三\): 不竞争条款](#)). These efforts have provided life sciences readers with additional strategic considerations when designing licensing transaction terms.

At the beginning of 2026, to help readers better understand the characteristics and changes in key terms of licensing transactions over the past year and gain insights into the evolving trends of China's life sciences market in the year ahead, we have reviewed the key licensing and NewCo projects handled in 2025, with reference to two previously published annual transaction data reports (please refer to: [2024 Data Analytics: China Life Sciences NewCo & Licensing Terms](#) and [2022 – 23 Data Analysis on China Life Sciences Licensing Key Terms](#)). In this article, we will present a comparative analysis across seven key dimensions, including marketing authorization rights, license grant, financial terms, intellectual property, diligence obligation, exclusivity, and termination rights, to summarize key trends and practical highlights from the past year, providing reference for future industry collaboration strategies and global expansion plans⁷.

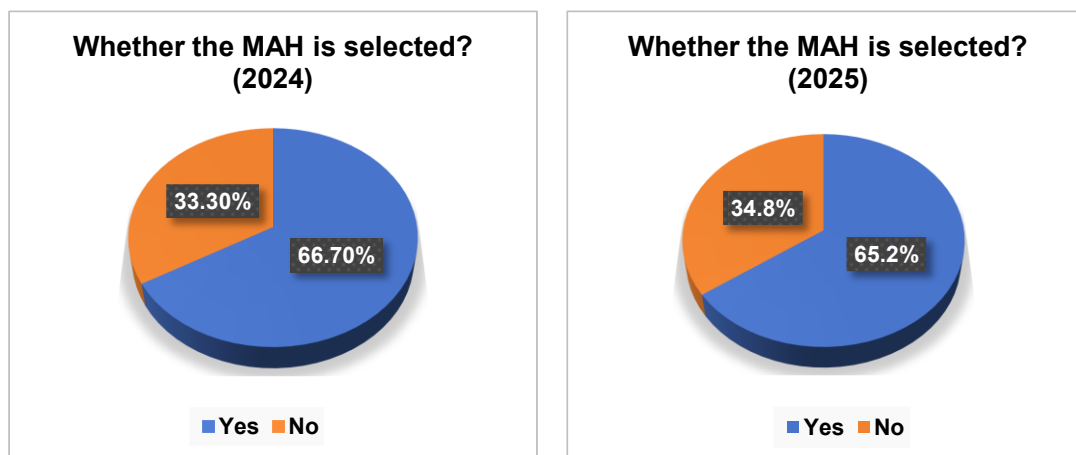
Marketing authorization rights

Under the pharmaceutical and medical device regulatory framework, the system of Marketing Authorization Holders, including drug marketing authorization holders and medical device registrants or filers (collectively referred to as “MAH”), plays a critical role as the primary entities responsible for ensuring the safety, efficacy, and quality control of pharmaceutical and medical device products throughout their entire lifecycle.

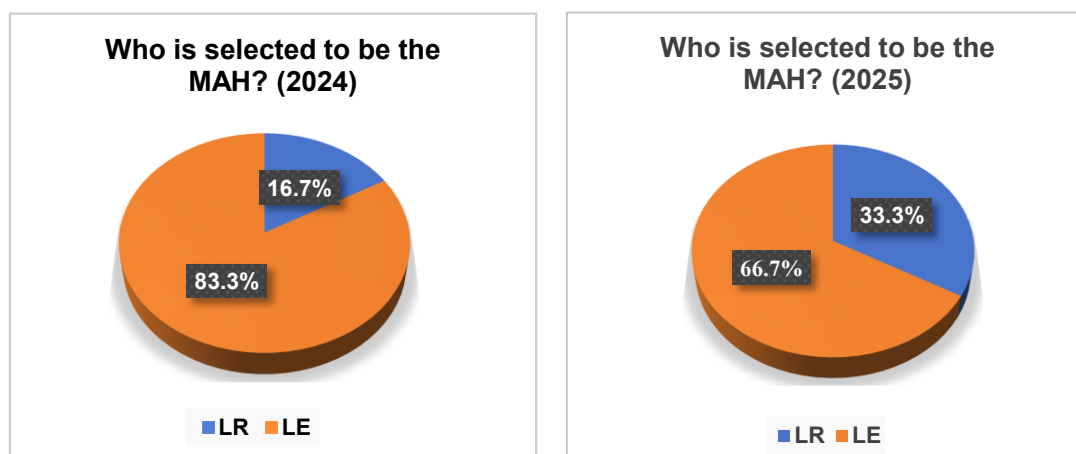
According to statistics, in over half (approximately 65.2%) of licensing transactions in 2025, the parties explicitly agreed in the license agreement that one party (or its designated party) would serve as the MAH for the licensed products within the territory of use, while the remaining approximately 34.8% of projects did not specify such an arrangement. This data continues the trend observed in 2024, where most projects proactively define the MAH role during the agreement phase, while the rest arrange it separately during execution. Similar to 2024, projects that do not pre-determine the MAH typically involve two scenarios: (i) the product is still in an early stage such as pre-IND, making it premature to designate an MAH; or (ii) the partners agree to select the MAH at a later stage depending on project progress. Furthermore, among the NewCo projects included in this analysis, most did not clearly specify the entity responsible for serving as MAH, likely due to the early development stage of these projects and

⁷ This article is an important work product and copyright of Han Kun and should be treated as confidential information of the firm. The data presented in this article are all derived from licensing-related transactions and NewCo projects in which the author has been involved in recent years. This article should not be relied on as legal advice or regarded as a substitute for detailed advice in individual cases. If you have any further questions or need professional legal services or support, please feel free to contact us.

uncertainties regarding future transaction structures.



Among projects where a MAH has been selected, 66.7% of license agreements designate the licensee (“Licensee” or “LE”) as the MAH for the licensed products in the territory of use, while the remaining 33.3% assign this role to the licensor (“Licensor” or “LR”). In practice, some agreements also provide one party with the right to designate an affiliate or third party to serve as MAH.



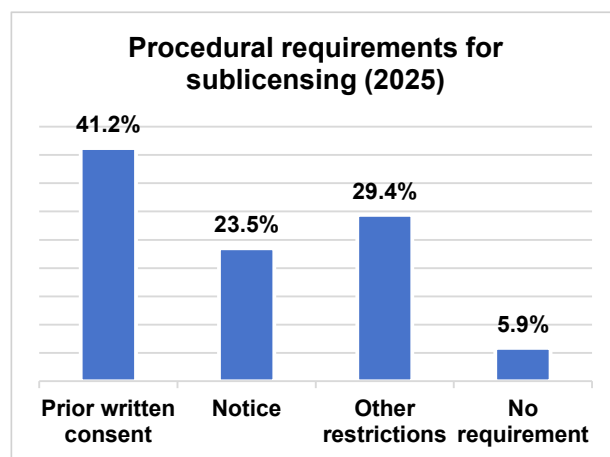
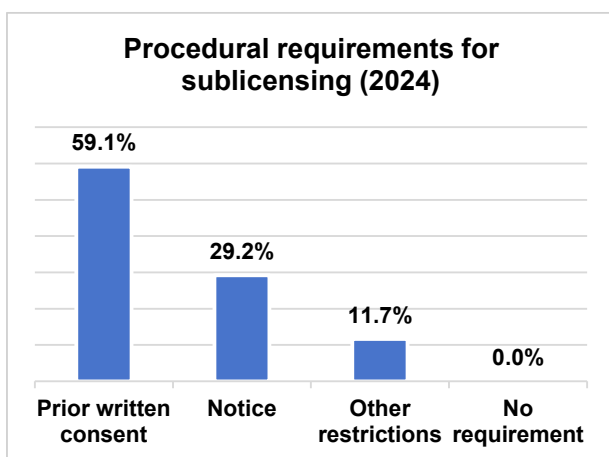
Compared to 2024, in 2025 the proportion of projects where the Licensor and Licensee serve as the MAH is closer, reflecting a more flexible and diverse approach to MAH arrangements based on commercial needs. Decision-making is increasingly driven by practical requirements rather than fixed models. Taking China as an example, with the continuous refinement of the MAH and local responsible entity systems in the pharmaceutical and medical device sectors, relevant enterprises have gained a deeper understanding of regulatory requirements. As a result, it is operationally feasible for either the Licensor or Licensee to act as the MAH, providing both parties with relatively ample freedom of choice.

License grant

I. Sublicensing

In the licensing transactions of 2025, the vast majority (approximately 89.5%) allow the Licensee to grant sublicenses, consistent with previous trends. Among these, only 5.9% of projects impose no

procedural restrictions on sublicensing; about 23.5% require the Licensee to notify the Licensor prior to granting a sublicense; and the largest share, approximately 41.2%, require prior written consent from the Licensor. Additionally, around 29.4% of projects impose further substantive restrictions on sublicensing, including customized conditions such as limitations on sublicensees (“**Sublicensees**”), allocation of responsibilities post-sublicensing, revenue sharing, and information disclosure. For instance, requiring the Licensee to assume responsibility for the actions of Sublicensees, disclosing redacted sublicense terms to the Licensor, restricting sublicenses solely to manufacturers, or making sublicensing contingent on specific revenue terms.



In the NewCo projects covered by this analysis, most require the Licensee to obtain the Licensor’s prior written consent before granting any sublicenses. This arrangement is closely tied to the unique transaction structure and collaboration mechanism of the NewCo model. Under this model, the Licensor, as an equity holder of NewCo, shares downstream R&D risks and financial pressures with its partners, resulting in a high degree of alignment between returns and risks. Therefore, establishing a prior approval mechanism for sublicensing not only helps control the parties to whom technology is licensed and how it is used but also provides flexibility to support resource synergy and efficient project advancement while safeguarding core interests.

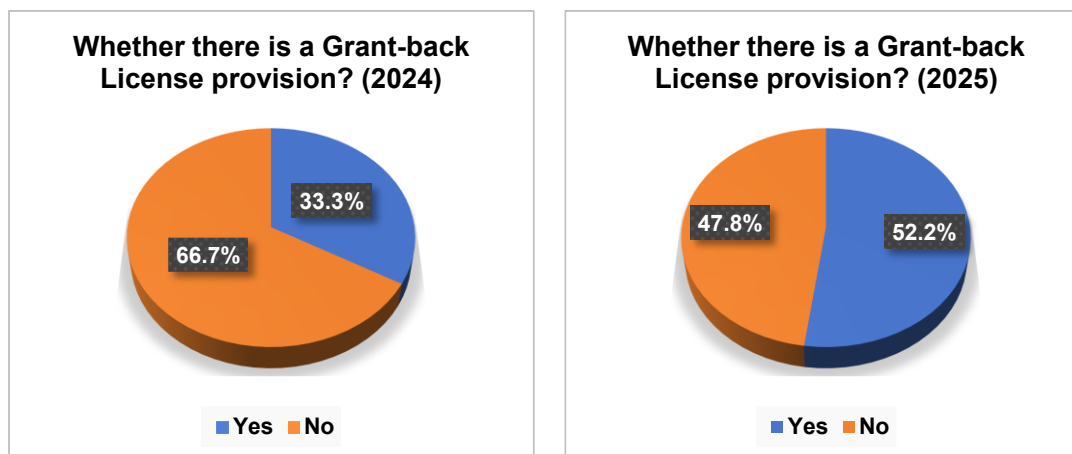
In 2024, only about 11.7% of projects included special provisions such as restrictions on Sublicensees in their sublicensing terms; this proportion increased to 29.4% in 2025. The share of such customized arrangements continues to grow, with increasingly diverse content. This trend clearly indicates that Licensors are placing greater emphasis on potential Sublicensees and their intended uses, showing a clear preference for more refined, market-adaptive collaboration structures and clause designs, along with enhanced management and protection of pipeline assets.

As outbound transactions by Chinese innovative pharmaceutical companies become increasingly frequent and complex, the parties can engage in deeper and more forward-looking negotiations with the support of cross-border transaction experts. By customizing key mechanisms such as sublicensing, they can not only effectively manage risks but also flexibly align with their respective global strategies and development goals, ultimately achieving mutual benefits.

II. Grant-Back License

In licensing transactions, the Licensee, especially a pharmaceutical company with strong clinical and product development capabilities, is not only the payer but also a significant contributor to R&D. Its contributions to expanding indications and improving processes for the transferred products and technologies are highly valuable. To maximize the utilization of technological value, in addition to granting the Licensee the license to use (“**Forward License**”), the Licensor sometimes also requires the Licensee to grant back new developments derived from the licensed technology (including improved technology or new intellectual property rights) to the Licensor (“**Grant-Back License**”). This Grant-Back License arrangement enables the Licensor to gain further technological advantages beyond the original scope of the license.

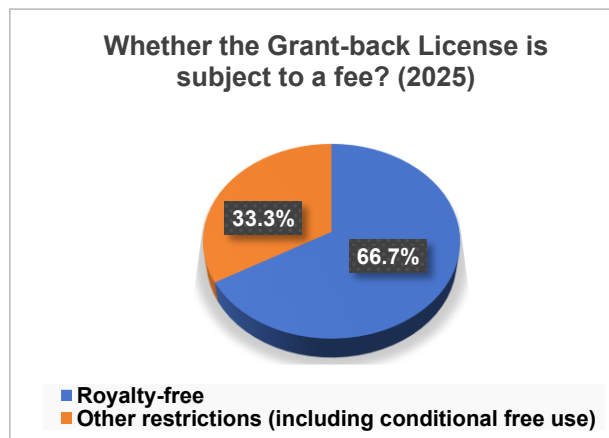
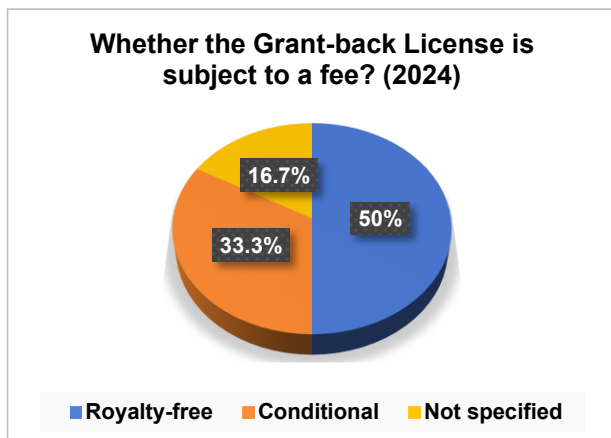
Transaction data from 2025 reveals a significant shift in this clause: approximately 52.2% of projects now explicitly include Grant-Back License terms, exceeding half for the first time. Compared to the previous years (about 40.7% in 2022 – 2023 and about 33.3% in 2024), this upward trend indicates that Grant-Back Licensing is transitioning from a special arrangement to a standard configuration, reflecting enhanced bargaining power and improved negotiation standing of the Licensor. Specific demands and clause designs regarding Grant-Back License are typically closely tied to the fundamental purpose of the collaboration, target products, business strategies of the parties, and market demands. For example, whether the Licensor plans continuous development within the same technology field or intends to commercialize the same product in markets outside the licensed territory will directly determine the scope, nature of rights, and consideration structure of the Grant-Back License.



In the NewCo projects included in this analysis, the proportions of projects that permit and prohibit Grant-Back Licenses by NewCo are roughly equal. This suggests to some extent that under the NewCo model, there is no consistent industry practice regarding the inclusion of Grant-Back License provisions. Instead, such arrangements may be more influenced by the commercial needs of the project and the negotiating positions of the parties, reflecting essentially a dynamic balance between control and revenue distribution by the transacting parties.

Among projects that have agreed on a Grant-Back License, the majority (approximately 66.7%) provide for royalty-free authorization. The remaining agreements (about 33.3%) do not specify monetary

compensation but instead establish diverse non-monetary consideration terms, such as limiting the scope of authorization to specific regions or technology fields, or imposing restrictions on the rights under Grant-Back License, including prohibitions on assignment or further sublicensing.



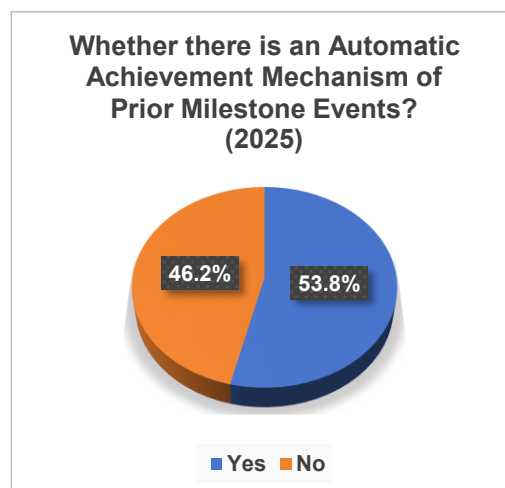
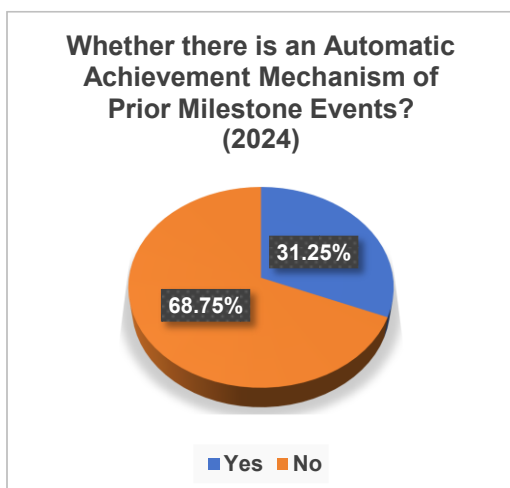
We believe that transaction trends in 2025 further indicate that licensing transactions are no longer simple asset transfers but represent opportunities for the parties to complement each other’s strengths in technology resources, R&D, and commercialization capabilities for collaborative development. When the Licensor and Licensee are respectively responsible for product development in different regions, cooperation through Grant-Back Licensing enables the Licensor not only to gain economic returns from the development of licensed products but also to enhance its own product development capabilities within specific regions, thereby more fully realizing the strategic value of pharmaceutical licensing transactions.

Financial terms

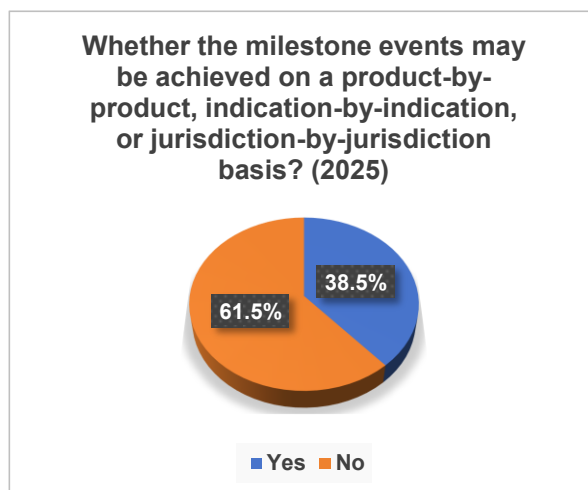
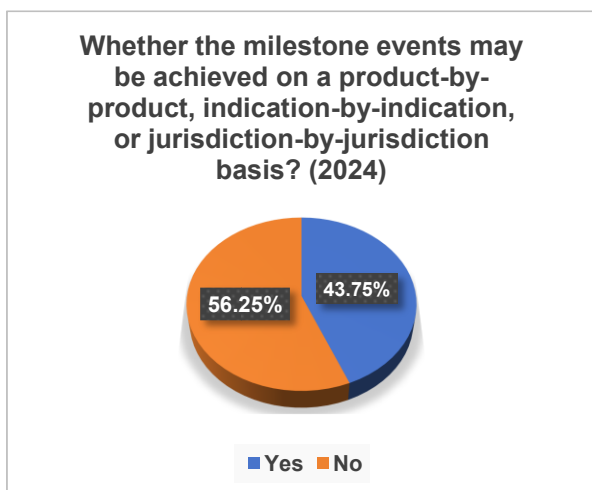
I. Milestone payment

In the licensing transactions analyzed in this article, the vast majority include milestone payment provisions. We conducted an in-depth analysis of the specific design of these provisions.

Under some licensing agreements, when a later milestone event is triggered, all prior milestone events are considered to be achieved automatically. As a result, the Licensee is required to pay the amount corresponding to the triggered milestone event as well as all prior milestone events (“**Automatic Achievement Mechanism of Prior Milestone Events**”). Based on historical data, among all projects with milestone payments, the proportion of those agreeing to Automatic Achievement Mechanism of Prior Milestone Events has steadily increased from 17.6% in 2022 – 2023 and 31.25% in 2024 to approximately 53.8% in 2025, surpassing half for the first time. The steadily rising adoption rate of the Automatic Achievement Mechanism of Prior Milestone Events reflects its evolution into a key tool for safeguarding the financial interests of the Licensor in a rapidly growing and increasingly complex licensing market. The Automatic Achievement Mechanism of Prior Milestone Events prevents benefit deadlocks caused by simultaneously or prematurely achieving specific milestones, thereby enhancing the predictability of payment triggers and project returns, and avoiding disputes over milestone achievement and corresponding payment obligations.



From the perspective of milestone events, approximately 38.5% of the agreements allow milestone events to be triggered multiple times or configured differently on a product-by-product, indication-by-indication, or jurisdiction-by-jurisdiction basis. The remaining approximately 61.5% of agreements adopt a one-time trigger structure for milestones without differentiation by product, indication, or jurisdiction. The proportion of agreements differentiating by product, indication, and jurisdiction has slightly declined compared to the 2024 statistical result (43.75%). The milestone payment arrangements reflect varying commercial considerations across different scenarios. This underscores companies' deepening expertise in global markets, specific indications, and their respective products. This enhanced understanding is manifested in increasingly complex and diverse contractual provisions.



Based on the current statistical results, NewCo projects generally define milestone events on an indication-by-indication basis and adopt a multi-tiered milestone structure encompassing development, regulatory, and sales stages. Since the licensed technology will become NewCo's sole or core asset upon establishment, the valuation of NewCo by its collaborator will substantially depend on an accurate assessment of the technology's market potential and prospects across different indications. Given the significant differences in R&D investment, regulatory uncertainty, and market potential among indications, setting milestones by indication facilitates a more precise alignment of risks and returns.

Meanwhile, establishing staged payment points based on progress in development, registration, and commercialization also helps strengthen positive incentives for project advancement and provides process controls to promote NewCo's growth.

It should be noted that differentiated milestone payment arrangements do not necessarily enable the Licensor to receive payments faster. If milestone payments are divided by jurisdiction, product, or indication, net sales for each jurisdiction, product, or indication must be calculated separately, which may extend the time required to trigger an individual milestone payment. We recommend customizing financial terms to match the specific needs of the parties according to commercial objectives and actual circumstances.

In addition, different agreements may include various types of milestone clauses, such as development milestones, sales milestones, patent filing milestones, diligence milestones, regulatory milestones, and milestones for inclusion in the National Reimbursement Drug List. These milestone clauses can be established individually or in combination to meet the specific requirements of the transaction parties.

II. Royalty

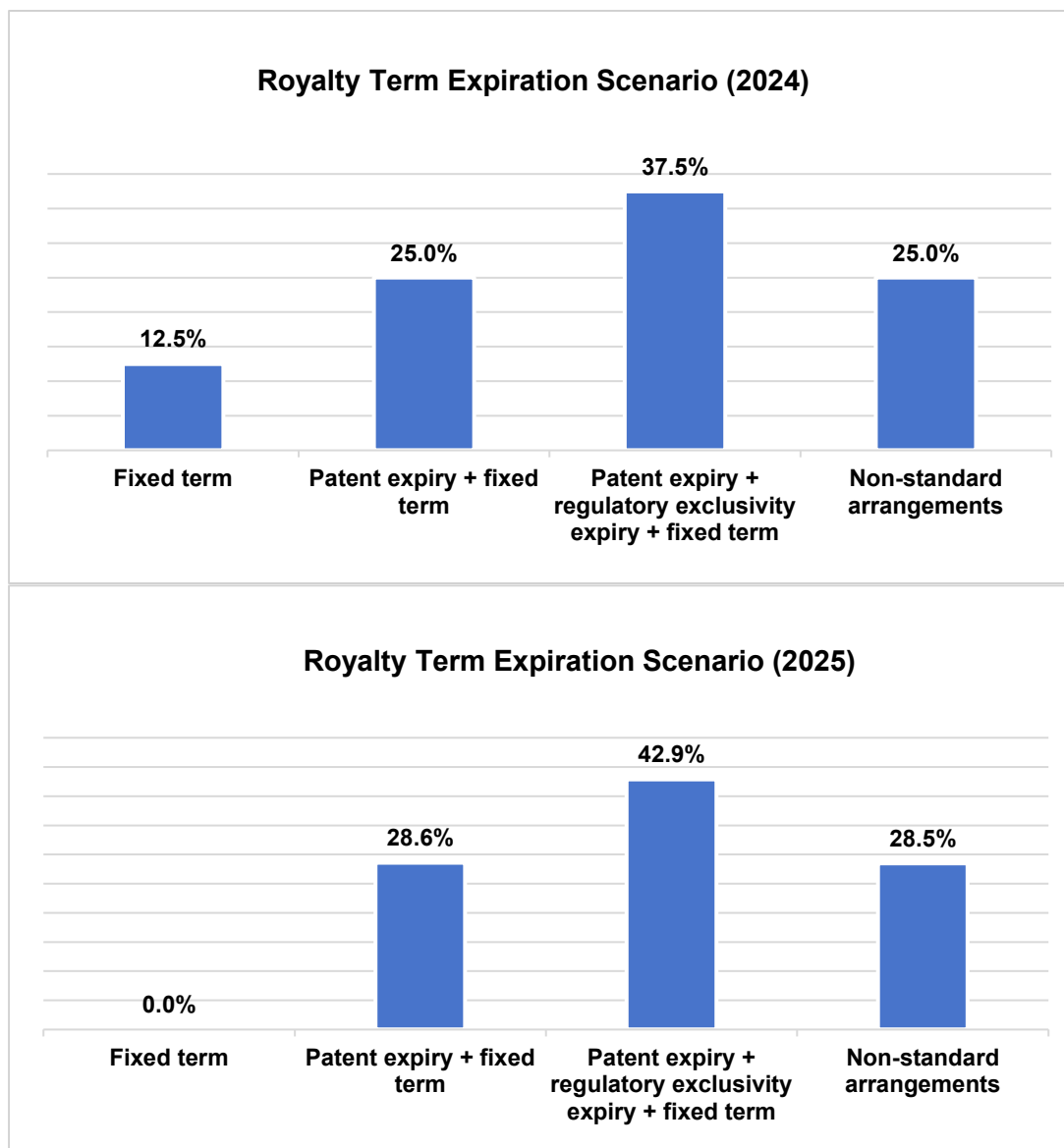
In the licensing transactions included in this statistical analysis, approximately 70.0% of the agreements specified royalty payments, while about 30.0% either did not include or explicitly excluded royalties. Overall, royalties remain a core component of the commercial return structure in licensing transactions, although a significant proportion of deals achieve returns through upfront payments, milestone payments, or equity arrangements, resulting in diversified structures.

For projects involving royalty payments, we further analyzed key elements such as the royalty term and calculation base.

Regarding the royalty term, the start date is typically the first commercial sale of the licensed product, while the end date varies and is often closely tied to the product lifecycle. Common termination conditions include patent expiry or the expiration of regulatory exclusivity. In practice, a fixed term measured from either the first commercial sale or the agreement signing date is also frequently specified as the royalty term. In this analysis, all cases include "patent expiry" as one of the termination triggers. Among them, approximately 42.9% of the projects define the termination date as the latest of "patent expiry, regulatory exclusivity expiry, and a fixed term"; about 28.6% adopt the later of "patent expiry and a fixed term" as the endpoint. Additionally, roughly 28.5% of cases incorporate non-standard triggers on top of conventional termination conditions, such as achieving a specific sales threshold. Compared to 2024, the distribution of different royalty termination structures remains largely unchanged, indicating that current royalty term designs in licensing transactions have become mature and stable. As patents fundamentally determine a product's commercial lifecycle, using patent expiry as the anchor point for royalty termination has become an industry consensus. Furthermore, supplementary mechanisms like sales thresholds and cumulative caps serve a consistent role as complementary tools beyond standard terms, resulting in their relatively stable prevalence across the sample.

Consistent with 2024, regarding the royalty base, the vast majority of projects use net sales as the

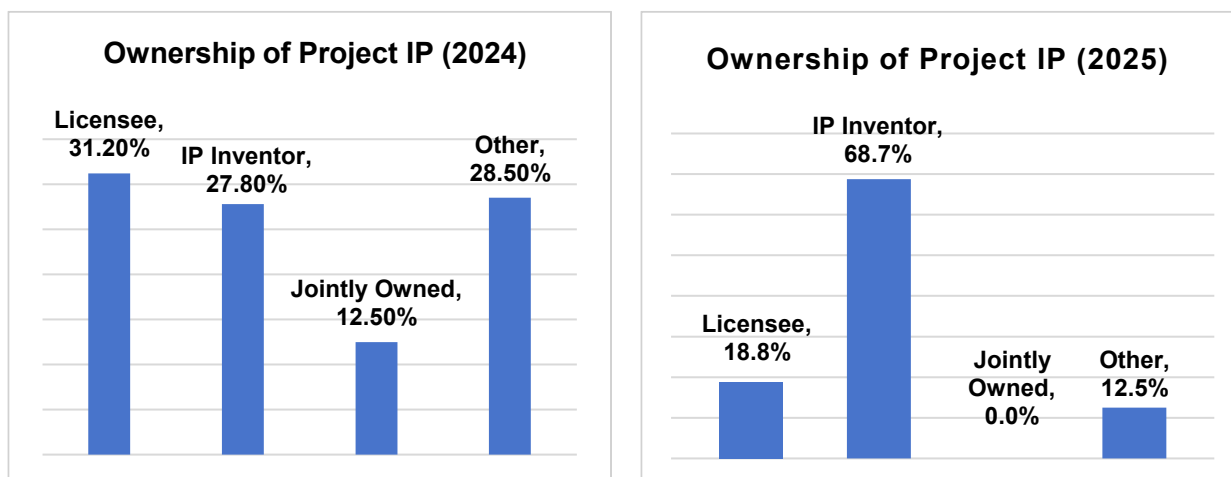
calculation basis, with only a small number using gross sales or the total invoice amount for the Licensee’s sales of licensed products to third parties. Net sales serves as a well-established benchmark across industries and regions, offering a mature definition that easily aligns with the Licensee’s financial system. In current transactional practice, using net sales as the royalty base remains the most common and mainstream approach.



Intellectual property

I. Ownership of Project IP

Compared to previous years’ statistics, the current data show that the percentage of projects adopting the principle of “ownership by the inventor” has reached 68.7%, significantly higher than in 2024 (27.8%) and 2022-2023 (29.6%). The proportion of projects explicitly specifying that exclusive ownership of the project intellectual property (“**Project IP**”) belongs to the Licensee has decreased from 31.2% in 2024 to 18.8%.



It is worth noting that, among the licensing transactions in 2025, relatively few projects explicitly stipulate that the ownership of Project IP is directly co-owned by both parties. More commonly, the relevant agreements do not establish a direct co-ownership arrangement for Project IP; instead, they adopt the principle of “ownership by the inventor”, with further provisions specifying that any results generated through joint efforts of the parties shall be jointly owned. Such arrangements account for 37.5% of the projects. In addition, certain projects adopt more flexible approaches to the allocation of Project IP, taking into account factors such as the exercise of option rights and the timing of the establishment of joint venture entities. These arrangements are more frequently observed in complex transaction scenarios such as collaborative R&D arrangements and pipeline spin-offs.

Overall, the key logic underlying the allocation of ownership of Project IP in 2025 has not substantially changed compared to previous years. The increasing proportion of projects adopting the principle of “ownership by the inventor” reflects a growing consensus between the parties on the distribution of collaborative outcomes, particularly in projects involving joint development and respective responsibilities for product development and commercialization within certain territories. It also demonstrates greater respect for each party’s interests in project and product development outcomes within their respective regions and areas of responsibility. At the same time, such allocation of ownership of Project IP still allows room for adjustments based on each party’s commercial interests, core technology protection needs, and negotiating positions.

II. Responsible party for IP prosecution, maintenance, enforcement, and defense

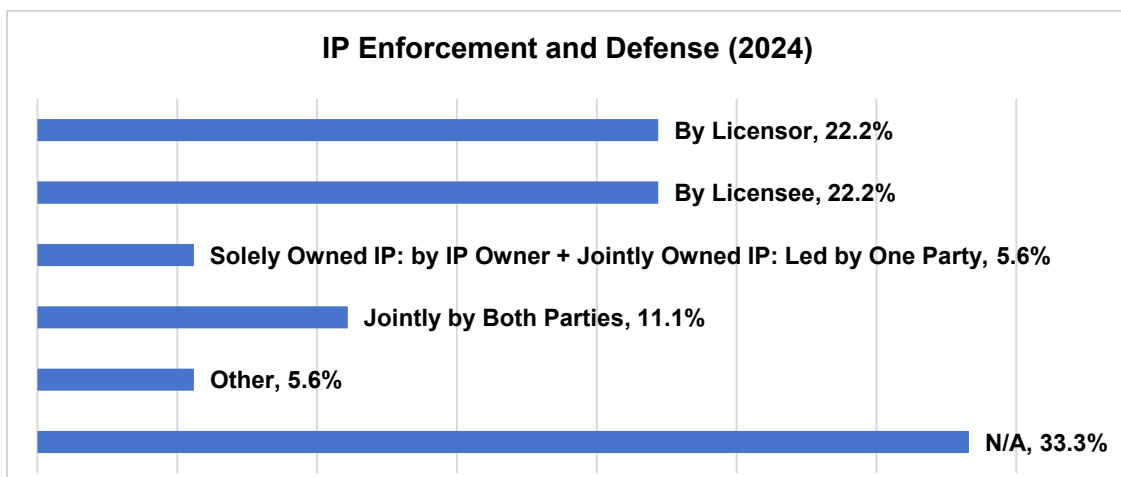
According to the statistics in 2025, the overall framework governing IP prosecution, maintenance, enforcement, and defense against third-party infringement remains stable, continuing the longstanding approach under which such responsibilities are predominantly allocated to a single party.

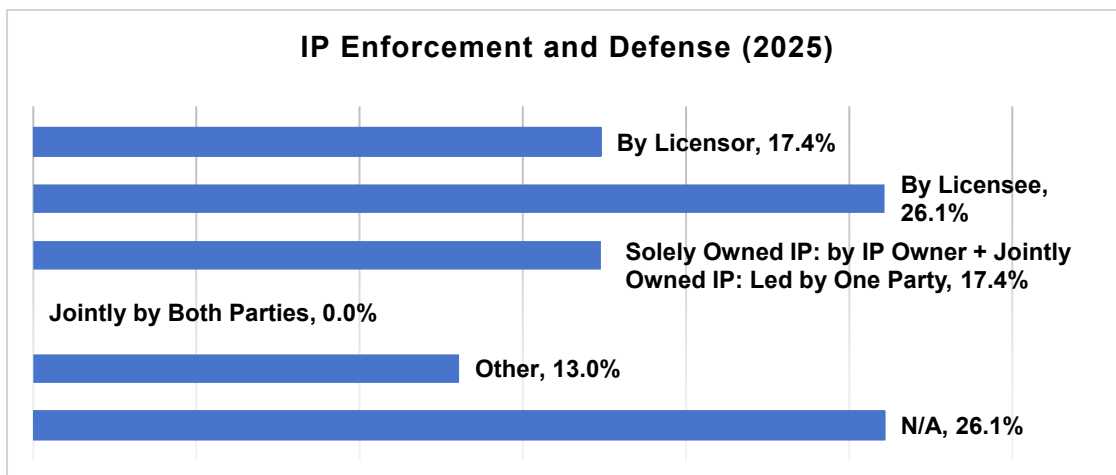
With respect to the prosecution and maintenance of IP, approximately 17.4% of the projects provide that such responsibilities are borne solely by the Licensor, largely consistent with the 2024 data. Approximately 21.7% of the projects allocate these responsibilities solely to the Licensee, representing a decrease from 31.8% in 2024. Projects that do not expressly allocate responsibility for IP prosecution and maintenance account for approximately 30.4%, remaining broadly in line with the 31.8% reported in 2024. By contrast, arrangements that allocate responsibilities based on ownership of the

relevant IP have increased significantly, rising from 4.5% in 2024 to 21.7%. The overall proportion of other allocation approaches has correspondingly declined.

Regarding the IP enforcement and the defense against third-party infringement, arrangements expressly providing for joint responsibility of the parties remain relatively uncommon, reflecting the practical need among parties to licensing transactions for clearly defined allocations of responsibility. By contrast, arrangements under which one party takes primary responsibility are more prevalent, accounting for approximately 43.5% of the projects, although this represents a slight decline from 44.4% in 2024 and 48.1% in 2022 – 2023. More specifically, projects in which enforcement and defense responsibilities are borne entirely by the Licensor account for 17.4%, while those in which such responsibilities are borne entirely by the Licensee account for 26.1%. At the same time, the number of projects that distinguish between solely owned IP and jointly owned IP for purposes of allocating enforcement and defense responsibilities has increased significantly, with the proportion rising from 5.6% in 2024 to 17.4%. It should be noted, however, that within such arrangements, the proportion of projects that expressly designate a specific party to take responsibility for the enforcement and defense of jointly owned IP has declined. Other enforcement arrangements (such as allocation by territory or determination through mutual consultation) have not experienced any material change, while the proportion of projects that do not expressly specify the responsible enforcement party has decreased from 33.3% in 2024 to 26.1%.

In summary, the above changes in both the types and proportions of IP arrangements reflect the practical need of the parties to licensing transactions to further refine the allocation of responsibilities for IP prosecution, maintenance, enforcement, and defense. Nevertheless, overall market practice continues to follow the longstanding approach under which such responsibilities are predominantly borne by a single party.



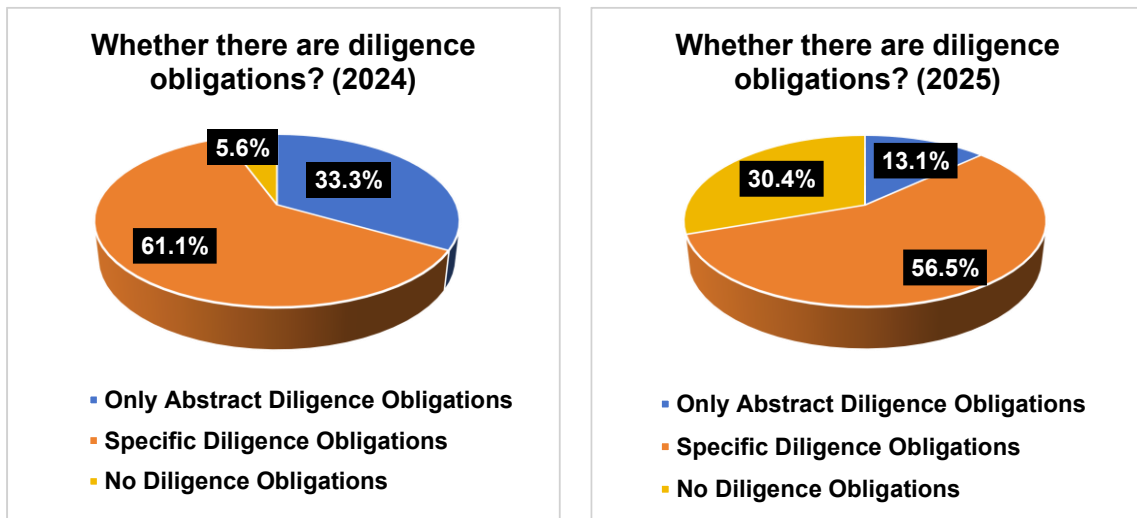


Diligence obligation

In order to ensure that the licensed product can be successfully and timely marketed to achieve commercial value, the agreements typically include a diligence obligation for the Licensee (or both parties in cross-licensing or co-development projects) regarding product R&D and commercialization.

Compared with statistics from prior years, approximately 69.6% of the agreements surveyed in 2025 contain express diligence obligations, remaining broadly consistent with the 66.7% reported in 2022 – 2023 but representing a decline from 94.4% in 2024. This, however, does not suggest that the performance of diligence obligations by either party has become uncommon in collaborative arrangements. Rather, the parties may have addressed diligence expectations through other contractual mechanisms, including linking certain financial terms to development and commercialization milestones, requiring the periodic submission, review, and discussion of development reports, and providing for matters subject to joint decision-making. As a result, the performance of diligence obligations has effectively become an inherent element of the overall contractual framework.

Meanwhile, about 13.1% of the projects only specify relatively abstract standards for diligence obligations, such as “Commercially Reasonable Efforts” or “Best Efforts”. By contrast, approximately 56.5% of the agreements either directly establish, or build upon such standards to include, more specific diligence obligations, such as the incorporation of diligence milestones, with a view to incentivizing the Licensee to actively perform its obligations and advance the relevant product pipeline. This trend reflects a growing preference among Licensors for more detailed and operationally enforceable diligence obligation provisions.

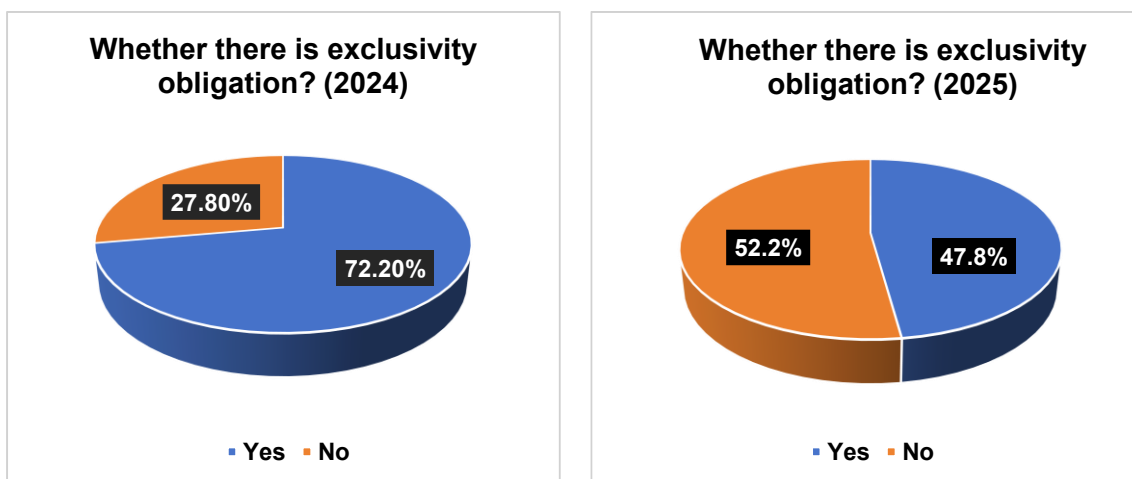


It is worth noting that the vast majority of NewCo projects also include clearly defined diligence milestone provisions. This primarily stems from the structural and objective-specific characteristics of the NewCo model. On one hand, NewCo typically serves as an incubator for specific pipelines or assets, and such technology represents the sole or core asset through which NewCo’s valuation appreciates. In this context, the abstract standard of Commercially Reasonable Efforts is insufficient to meet project timeline management needs, whereas quantifiable and verifiable diligence milestones help anchor the project pace and ensure execution remains on track. On the other hand, the governance structure of NewCo is often relatively independent from both parties, with the potential for third-party investors to participate, leading to higher demands for transparency in project progress. Compared to the standard of Commercially Reasonable Efforts, clearly defined diligence milestones are more conducive to enhancing the overall controllability and stability of the transaction structure.

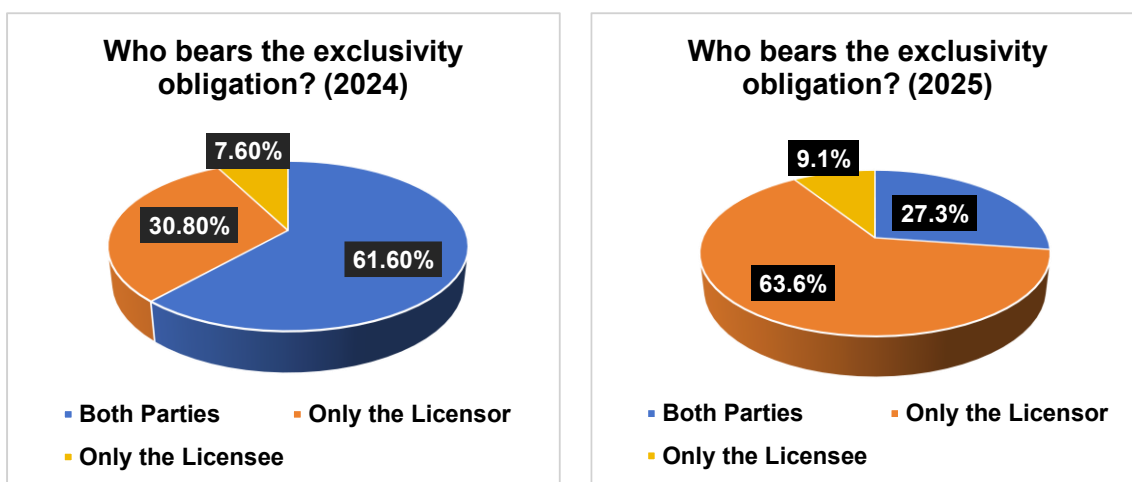
In addition, in agreements that stipulate specific diligence obligations, approximately 30.8% explicitly link such duties to the right to terminate the agreement. For example, if a key milestone is not achieved, the Licensor may terminate the collaboration as stipulated, and then independently advance development or grant rights to a third party. This arrangement makes the diligence milestone a core restrictive provision during the project, strengthening the Licensor’s oversight and control over the research, development, and commercialization process. At the same time, for the Licensee, this increases project pressure and introduces a certain level of instability regarding the use of the licensed technology. Given the significant impact of such provisions on the parties, detailed discussions during negotiations are necessary regarding how diligence milestones are triggered, specific requirements, and any exceptions or exemptions.

Exclusivity

To ensure effective collaboration between the parties in the development and commercialization of the licensed product while maximizing overall returns, licensing agreements typically include explicit provisions on exclusivity obligations. These provisions are designed to prevent any actions that may adversely affect the rights and interests of the other party. According to statistics, 47.8% of agreements explicitly include exclusivity obligations, representing a decline from 72.2% in 2024 and 63% in 2022 – 2023.



Among the projects that include exclusivity obligations, arrangements under which both parties are subject to mutual exclusivity obligations account for approximately 27.3%, representing a significant decrease compared with 61.6% in 2024 and 64.7% in 2022 – 2023. By contrast, projects in which the Licensor alone is subject to exclusivity obligations account for approximately 63.6%, reflecting a marked increase from 30.8% in 2024 and 23.5% in 2022 – 2023. Projects in which the Licensee alone bears exclusivity obligations account for approximately 9.1%, showing only modest fluctuations compared with 7.6% in 2024 and 11.8% in 2022 – 2023.



Compared with data from previous years, the proportion of projects in 2025 where the Licensee unilaterally assumes the exclusivity obligation remains generally stable. In contrast, arrangements involving mutual exclusivity obligations between the parties have decreased compared to previous years and no longer dominate. Instead, arrangements where the Licensor unilaterally assumes the exclusivity obligation have become more prevalent, imposing greater restrictions on the Licensor. This shift may be attributable to the continuous enhancement of innovation capabilities and pipeline competitiveness among Chinese pharmaceutical companies in recent years. As large multinational pharmaceutical companies increasingly act as Licensees and given their diversified existing pipelines and the likelihood of developing products for similar indications in the future, such Licensees typically seek a higher degree of control over the licensed pipeline and endeavor to avoid restrictions on their existing or potential future businesses. As a result, they are often reluctant to accept exclusivity obligation arrangements. In addition, based on

our observations, exclusivity obligation provisions constitute one of the more sensitive and heavily negotiated core terms in licensing transactions. The parties' positions in this regard tend to diverge significantly, leading to higher negotiation costs and making consensus more difficult to achieve.

For the reasons stated above, we understand that the establishment of exclusivity obligations is often closely related to the negotiating positions of the parties, as well as their pipeline assets and development strategies, and can have a profound impact on their future business planning and operations. Therefore, it is recommended that the parties carefully design such arrangements in light of their specific commercial needs during negotiations and drafting of the agreement.

Termination rights

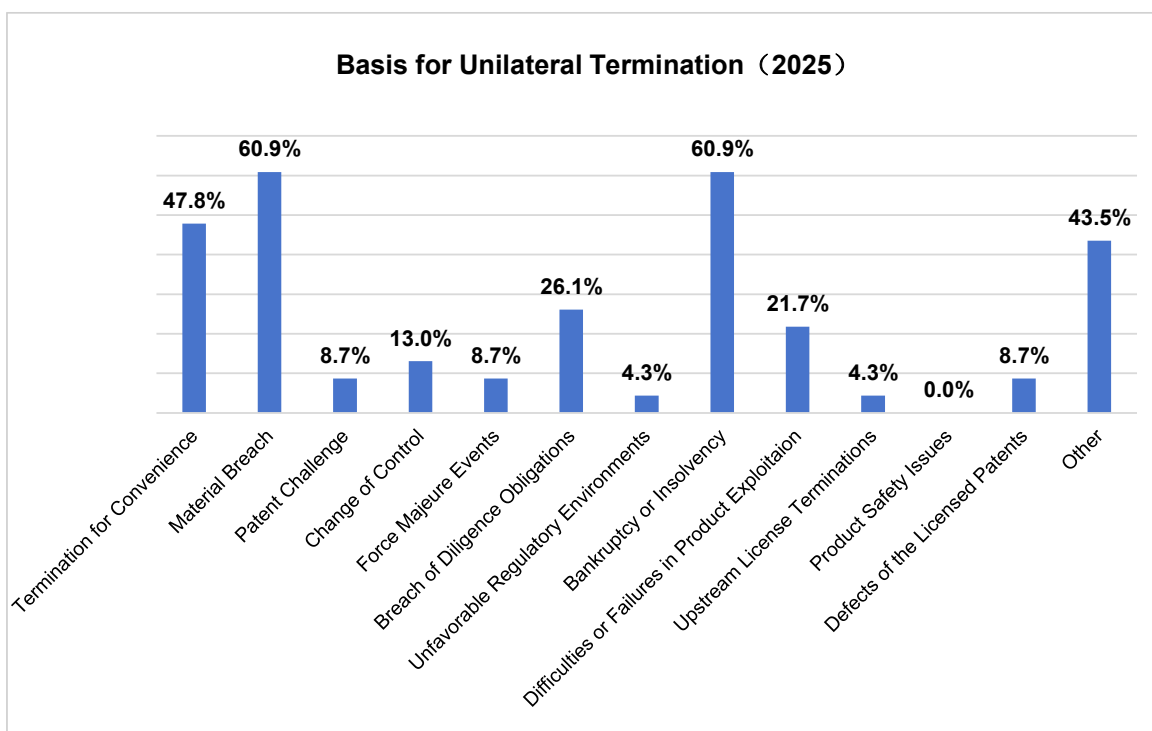
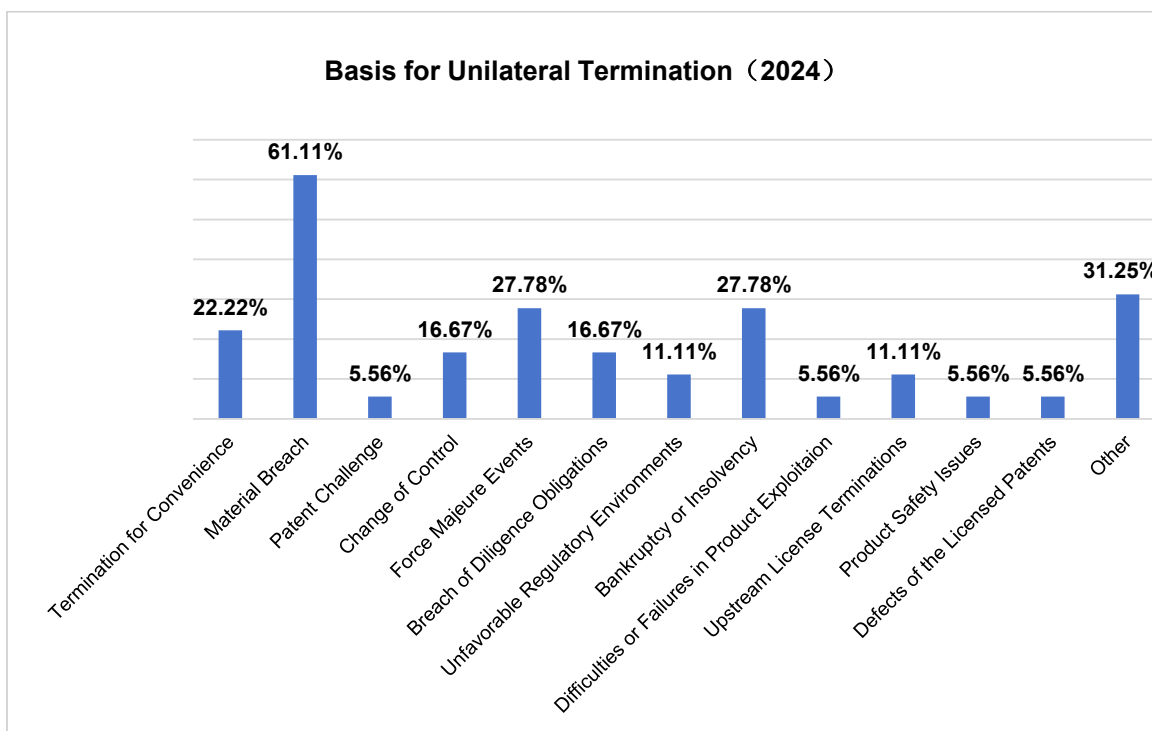
I. Unilateral termination right

According to the statistics in 2025, the party entitled to exercise the unilateral termination right remains largely unchanged compared to previous years, although there have been some adjustments in the types and proportions of triggering events.

From the perspective of the party entitled to exercise unilateral termination rights, 72% of the projects provide that both parties to the agreement are entitled to unilateral termination rights (regardless of whether the applicable termination grounds or exercise conditions are symmetrical), a structure that is largely consistent with prior years' practice. However, in a small number of projects, unilateral termination rights are granted exclusively to either the Licensor or the Licensee. In addition, among the projects that provide for termination for convenience, approximately 72.7% grant such termination-for-convenience rights solely to the Licensee, representing the most prevalent arrangement, while only approximately 9.1% of the projects provide that both parties are entitled to terminate for convenience. Notably, in certain projects, the exercise of termination-for-convenience rights is subject to specific preconditions, such as the payment of an upfront fee or the satisfaction of other specified conditions before such rights may be triggered. Such arrangements are more commonly observed in projects where termination-for-convenience rights are granted exclusively to the Licensee.

With respect to the grounds for exercising unilateral termination rights, the types of such grounds have become more diverse. "Material Breach" and "Bankruptcy or Insolvency" remain the most commonly specified termination grounds, each appearing in approximately 60.9%⁸ of the projects. In addition, approximately 47.8% of the agreements provide for termination for convenience, representing a significant increase from 22.22% in 2024. A smaller number of projects further include more specific termination grounds, such as disruptions in the manufacturing or supply of drugs or investigational drugs, failure to perform technology transfer obligations, and breach of exclusivity obligations, reflecting a more detailed and diversified range of termination grounds.

⁸ In certain statistics presented in this article, the total percentages may exceed 100% due to the inclusion of multiple overlapping categories in certain agreements.

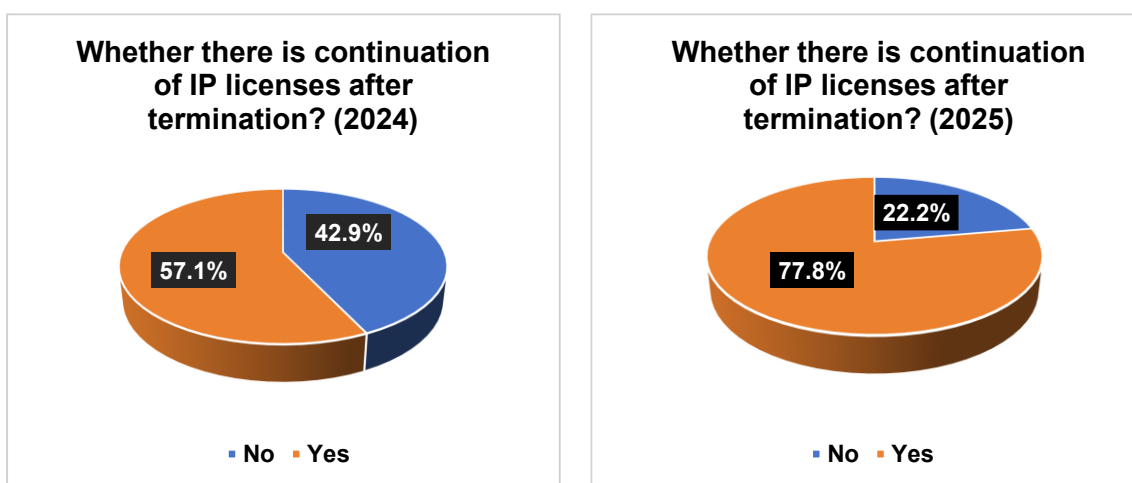


II. Termination consequences

Generally, upon termination of a license agreement, the licenses granted thereunder will automatically terminate. However, in certain projects, depending on the nature of the project or the specific grounds for termination, the parties may agree that the license will survive and remain in effect following termination of the agreement.

For example, among the projects that include post-termination licensing arrangements, approximately

77.8% of the projects provide that part or all of the licenses will remain in effect following termination. This represents a significant increase compared with 57.1% in 2024 and 29.6% in 2022 – 2023. Within this category, provisions under which the Licensor’s Forward License to the Licensee survives termination and provisions under which the Licensee’s Grant-Back License to the Licensor survives termination appear in similar proportions. Typical arrangements include, without limitation, an exclusive license granted by the Licensor automatically converting into a non-exclusive license upon termination, or the Licensee automatically granting a Grant-Back License to the Licensor following termination.



In addition, among the projects in which part or all of the licenses are agreed to survive following termination, approximately 33.3% of the agreements adopt conditional post-termination licensing arrangements. Such arrangements primarily include mechanisms under which termination triggers a consultation or negotiation process between the parties to determine whether the Forward License granted by the Licensor to the Licensee should continue or to renegotiate and define the terms of any Grant-Back License, as well as mechanisms under which the continuation of the license to the Licensee is automatically triggered based on the specific grounds for termination. Overall, compared with prior years, post-termination effect provisions in 2025 reflect a broader range of drafting approaches.

It is worth noting that, among the licensing transactions in 2025, projects that provide for continuing license arrangements are predominantly cross-licensing or collaborative R&D projects. In such projects, the parties typically develop a relatively high degree of technical interdependence during the cooperation period. As a result, even where an agreement is terminated for specific reasons, one party may still need to rely on the other party’s licensed technology in order to advance subsequent research, development, and commercialization activities. From the perspectives of risk allocation and value preservation, continuing license arrangements also help safeguard the R&D resources, capital, and time investments made by the parties during the cooperation period, and can, to a certain extent, provide continuity and stability for existing R&D results and commercial expectations. In addition, in practice, continuing license provisions are often tailored based on factors such as the grounds for termination, the applicable field, territory, and duration, thereby ensuring continuity in the use of licensed technology while avoiding the imposition of unreasonable long-term constraints on the other

party. Such a more flexible drafting approach also enhances the overall acceptability of continuing license provisions in negotiations.

Comparative summary of License-in/out and NewCo transactions in 2025 versus previous years

Based on the analysis of transaction data from 2025, Chinese companies acting as Licensors have demonstrated an unprecedentedly strong position in the term structuring and rights protection. This development underscores the increasing global recognition of the innovation capabilities of Chinese pharmaceutical companies and their enhanced negotiating leverage. Meanwhile, with greater transactional experience, market participants are engaging in more nuanced consideration of contractual details, resulting in licensing arrangements that are increasingly customized and adapted to specific deal contexts.

First, the enhanced position and strengthened bargaining power of Chinese companies as Licensors became a prominent feature of licensing transactions in 2025. In numerous licensing transactions we have participated in, it is evident that Chinese pharmaceutical companies are demonstrating stronger initiative and bargaining power during negotiations, successfully driving the formation of relatively favorable, long-term interest-oriented rights arrangements. **For example, they no longer routinely grant global rights to Licensees but instead choose to retain development, manufacturing, or commercialization rights in specific territories. In some cases, Licensee's exercise of termination-for-convenience rights is conditioned on prerequisites such as payment of upfront fees, thereby restricting the exercise of such rights. In practice, some Licensors have also implemented co-development revenue-sharing mechanisms that require Licensees to provide ongoing profit sharing. Moreover, some Licensors have pre-defined rights reversion mechanisms in the agreement and have indeed reclaimed project rights due to the Licensee's slow progress in clinical trials.** These arrangements not only generate significant cash flow for Chinese pharmaceutical companies but also reserve ample room for future development, further strengthening their foundation for participating in global innovation and commercial competition.

Second, with the accumulation of transaction experience, all parties have developed a deeper commercial understanding of individual projects and long-term development. This has led to clearer definitions of key interests during negotiations, thereby driving agreement terms toward greater refinement and scenario-specific customization. For example, some projects have implemented more comprehensive exit mechanisms, linking specific diligence obligations to termination rights, which preserve the parties' ability to limit losses and reclaim related technology. **Additionally, an increasing number of projects highlight Licensors' focus on long-term strategic planning. Rather than focusing solely on immediate transaction gains, these agreements include provisions for Grant-Back Licenses that allow Licensors to obtain newly developed IP (e.g., improvements) derived from the licensed technology by the Licensee, thus reserving space for subsequent technological iterations and sustainable development. Meanwhile, some projects have flexibly adopted non-monetary consideration approaches, controlling the impact of Grant-Back Licenses by limiting the licensed territory, technology fields, or scope of rights transfer, thereby better**

protecting the Licensee’s core interests and overall business layout. Furthermore, as disputes related to licensing transactions have gradually emerged—such as conflicts arising from unclear definitions of exclusivity obligations or disagreements over whether standards of diligence obligations have been met—market participants have been able to identify potential risk clauses through these cases and make preemptive adjustments in subsequent transactions. (In an arbitration case where one of the key issues was whether commercially reasonable efforts had been fulfilled, the Han Kun team successfully represented the Licensee in its defense, preserving substantial commercial benefits for the client. For details, please refer to: [Benchmark Victory for Arbitration Case on New Drug Development License-in, Successfully Defending Client’s Core Interests](#)).

In addition, due to the unique transaction structure of the NewCo model, transaction arrangements often require customized design. Being a transaction structure that merges licensing and equity investment, NewCo projects typically focus on a single pipeline with a high asset concentration. The development progress, financing arrangements, and potential exit pathways are characterized by significant uncertainty and flexibility. **Considering that different NewCos have varying establishment objectives, whether emphasizing capital infusion, integration of R&D capabilities, or acquisition of quality assets, the parties involved differ in their risk allocation, specific roles, and return expectations. Consequently, relevant terms such as rights of first negotiation often require targeted adjustments,** resulting in distinctly personalized term designs for NewCo projects.

In summary, transaction practices in 2025 demonstrate that Chinese pharmaceutical companies, leveraging continuously enhanced comprehensive competitiveness, are transitioning from mere “market participants” to influential “market shapers” in global collaborations. This shift is driving licensing transactions toward a more balanced and strategically mature stage that emphasizes long-term planning.

Conclusion

Based on 2025 transaction data and industry practices, this article systematically reviews and analyzes the current landscape, trends, and evolutionary logic of licensing transaction terms across seven key dimensions, including marketing authorization rights, license grant, financial terms, intellectual property, diligence obligation, exclusivity, and termination rights, and compares term design with the NewCo model. Overall, China’s biopharmaceutical licensing market is demonstrating a mature trajectory of rapid growth, with innovative models such as NewCo further enriching transaction structures and negotiation dynamics. In future deal negotiations and agreement drafting, parties should, while referencing prevailing practices, place greater emphasis on flexibly and prudently customizing terms according to specific commercial strategies, risk appetites, and collaboration contexts to build more resilient and sustainable partnerships.

4. Synergy & Rebirth: Reshaping Regulations for Bank M&A Loans

Authors: Ting ZHENG | Eryin YING | Shirley LIANG | Hattie ZHANG

On 31 December 2025, the National Financial Regulatory Administration (hereinafter referred to as the “**NFRA**”) officially issued the *Administrative Measures for the M&A Loans of Commercial Banks* (hereinafter referred to as the “**Official Measures for M&A Loans**”, 《商业银行并购贷款管理办法》). Prior to this, the consultation draft of these Measures (hereinafter referred to as the “**Draft Measures for M&A Loans**”) was issued for public comments on 20 August 2025. Building on a systematic summary of past regulatory practice in M&A Loans, the Official Measures for M&A Loans constitute a comprehensive revision and refinement of the existing regulations. The new Measures intend to formally replace the *Guidelines on Risk Management of Mergers and Acquisitions Loans of Commercial Banks* (hereinafter referred to as the “**2015 Guidelines**”, 《商业银行并购贷款风险管理指引》) issued by the China Banking Regulatory Commission (the “**CBRC**”).

This article will focus on outlining the main revisions in the Official Measures for M&A Loans, and flag out key points worth attention and propose recommendations for reference by relevant market participants regarding compliance and practical operations of banks’ M&A Loan business.

Evolution of M&A Loans Regulatory Rules

I. 2008: The Initial Breakthrough

On 6 December 2008, CBRC promulgated the *Guidelines on Risk Management of M&A Loans of Commercial Banks* (hereinafter referred to as the “**2008 Guidelines**”, 《商业银行并购贷款风险管理指引》), which broke through the principled restriction under Article 20 of the *General Rules of Loans* (《贷款通则》) issued in 1996 stating that borrowers “shall not use loans for equity investment, unless otherwise stipulated by the state” and allowed qualified commercial banks to launch M&A Loan businesses. This marked the complete lifting of the ban on commercial banks entering the onshore corporate M&A market. Prior to this, in practice, only some foreign funded banks and policy banks with special authorization from CBRC, were allowed to finance large state-owned enterprises for their offshore M&A activities. According to the Q&A of a CBRC officer regarding the 2008 Guidelines⁹, the issuance of these Guidelines was intended not only to respond to the international financial crisis and broaden enterprise financing channels, but also to serve as a prudent first step, striking a balance between meeting market demand and controlling banking risks.

II. 2015: First Optimization

In 2015, CBRC revised the 2008 Guidelines and issued the 2015 Guidelines, introducing three (3) key relaxations: (1) moderately extending the maximum tenor of M&A Loans from five (5) years to seven (7) years; (2) moderately raising the upper limit on the proportion of M&A Loan amount to the transaction consideration from 50% to 60%; and (3) revising the mandatory requirement for security on M&A Loans into a principle-based provision, while deleting the requirement that security conditions

⁹ <https://www.nfra.gov.cn/cn/view/pages/ItemDetail.html?docId=2981&itemId=915&generalType=0>.

shall be higher than those for other types of loans, to allow commercial banks to reasonably determine security conditions to prevent the risks of M&A Loans based on the risk profile of the M&A project and the credit status of the acquiring enterprise.

III. Recent Years: Pilot Explorations

In recent years, regulatory authorities have conducted small-scale innovations and explorations of M&A Loan regulations in specific regions and sectors through issuing relevant pilot policies, such as “non-resident M&A Loans in the Lin-gang Special Area” and “M&A Loans for technology enterprises”. These initiatives have accumulated valuable experience for this current comprehensive revision (detailed further in the subsequent sections).

IV. August 2025: Comprehensively Revised Draft Measures for M&A Loans

On 20 August 2025, NFRA comprehensively revised the 2015 Guidelines to form the Draft Measures for M&A Loans, in order to adapt to the development needs of the M&A market under new circumstances and to facilitate industrial transformation and upgrading. The main revisions in the Draft Measures for M&A Loans include:

- (1) **Broadening the application scope of M&A Loans:** on the basis of the 2015 Guidelines only applying to controlling M&A transactions (控制型并购交易), allowing M&A Loans to support equity participation M&A transactions (参股型并购交易) that meet certain conditions;
- (2) **Optimizing loan conditions:** raising the upper limit on the proportion of controlling M&A Loan amount to the M&A transaction consideration, and extending the maximum loan tenor;
- (3) **Establishing differentiated business qualification requirements:** for commercial banks conducting controlling and equity participation M&A Loan businesses, in addition to requirements such as sound regulatory ratings and compliance with key prudential regulatory indicators, further differentiated asset size requirements are imposed; and
- (4) **Emphasizing solvency assessments:** requiring banks to, after comprehensive consideration of risks related to M&A transactions, focus on assessing the solvency of the acquirer, and simultaneously, pay attention to the development prospects, synergies and operational benefits of the enterprise concerned after the M&A transaction, and assess the impact on M&A Loans from multiple dimensions.

V. December 2025: Official Issuance of the Official Measures for M&A Loans - Meticulous Refinement from Framework to Details

Compared to the Draft Measures for M&A Loans, the Official Measures for M&A Loans maintain the core reform framework while introducing refined adjustments characterized as “**one (1) relaxation, two (2) tightenings, and one (1) clarification**”, fully reflecting the regulators’ positive response to market feedback.

One (1) relaxation: Introducing flexibility in payment methods - the mandatory requirement under the *Draft Measures for M&A Loans* that payments “shall be made through entrusted payment” is adjusted to “shall, **in principle**, be made through entrusted payment” leaving room for special transaction scenarios in which entrusted payment is not feasible.

Two (2) tightenings: (1) The Official Measures for M&A Loans for the first time explicitly require that, for Enhancing Controlling M&A Loans (as defined below, 增强控制型并购贷款), the proportion of equity acquired by a single acquirer in a single transaction shall not be less than 5%; and (2) Article 29 of the Official Measures for M&A Loans lowers the concentration cap on M&A Loans to a single borrower from 5% (under the 2015 Guidelines and the Draft Measures for M&A Loans) to 2.5%, thereby significantly strengthening risk dispersion requirements.

One (1) clarification: Article 27 of the Official Measures for M&A Loans clarifies that, where M&A Loans are used by the acquirer to replace the M&A transaction consideration previously paid by the acquirer, the 1-year interval is calculated from the first drawdown date to the completion of full payment of the M&A transaction consideration to be replaced, which clarifies the concept of “loan processing date” and “the completion of payment of the M&A transaction consideration” in the Draft Measures for M&A Loans.

Key Points of the Official Measures for M&A Loans

To provide an intuitive comparison of the major changes among the Official Measures for M&A Loans, the Draft Measures for M&A Loans, and the 2015 Guidelines, the relevant provisions are set out in the table below (with ~~strikethroughs~~ and red text indicating the main differences among the three (3) rules, and blue text highlighting key differences between the Official Measures for M&A Loans and the Draft Measures for M&A Loans). On this basis, we have also proposed corresponding practical points of attention and recommendations.

I. Purpose of M&A Loans: restricting repayment of “expenses”

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
Paragraph 1, Article 3 “M&A Loans” under these Measures refer to loans granted by commercial banks to onshore acquiring enterprises or their subsidiaries for the purpose of paying the consideration for M&A transactions and (including transaction expenses) .	Paragraph 1, Article 3 “M&A Loans” under these Measures refer to loans granted by commercial banks to onshore acquiring enterprises or their subsidiaries for the purpose of paying the consideration for M&A transactions (including transaction expenses).	Article 4 “M&A Loans” under these Guidelines refer to loans granted by commercial banks to acquirers or their subsidiaries for the purpose of paying the consideration for M&A transactions and expenses.

Interpretation: Based on the 2015 Guidelines, the Draft Measures for M&A Loans narrowed the term “expenses” to “transaction expenses”, which triggered discussions within the industry regarding the scope of expenses that may be paid with M&A Loans. The Official Measures for M&A Loans revert to the original wording of the 2015 Guidelines, indicating that the scope of expenses payable with M&A Loans has not been changed. In practice, such expenses generally refer to taxes and expenses, as well as intermediaries fees (such as audit, valuation, and legal fees) related to M&A transactions, and do not include financing costs.

II. M&A Implementation Entity: emphasizing investment capacity requirement

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
Same as the Draft Measures for M&A Loans	Paragraph 2, Article 3 The “subsidiary” referred to in the preceding paragraph means a wholly-owned or controlled subsidiary of the acquirer which is mainly engaged in investment management.	Paragraph 2, Article 3 The M&A transaction can be carried out by the acquirer through a wholly-owned or controlled subsidiary which is specifically established without other business activities (hereinafter referred to as the “subsidiary”).

Interpretation: Paragraph 2, Article 3 of the 2015 Guidelines expressly provides that the M&A implementation entity can be a wholly-owned or controlled subsidiary of the acquirer “which is specifically established without other business activities”. However, Paragraph 2, Article 3 of both the Official Measures for M&A Loans and the Draft Measures for M&A Loans revise the scope of the M&A implementation entity to a wholly-owned or controlled subsidiary of the acquirer “which is mainly engaged in investment management”. We understand that the regulatory intent is to ensure that the M&A implementation entity and/or the borrower under an M&A Loan shall possess the corresponding investment expertise, management experience and capacity to assume liabilities. When determining whether the relevant entity possesses the aforementioned capabilities, various factors may be taken into account, including its business scope, historical investment performance and financial statements may be considered comprehensively. With respect to shell companies established solely for the purpose of an M&A transaction, we currently tend to believe that they will not satisfy the requirements under the Official Measures for M&A Loans.

Regarding whether an offshore subsidiary of the acquirer can serve as the M&A implementation entity, during the implementation period of the 2015 Guidelines, there were numerous precedents where banks provided M&A Loans to the offshore subsidiaries of onshore acquirers, and further to the 2015 Guidelines, the Official Measures for M&A Loans do not impose any restriction on the place of incorporation of the M&A implementation entity. Thus, we tend to take the view that, banks may provide M&A Loans to the offshore subsidiaries of onshore acquirers under the Official Measures for M&A Loans, provided that applicable foreign lending regulations are observed. It is worth noting that, in accordance with Article 7 of the *Circular of the People’s Bank of China and the State Administration of Foreign Exchange on Relevant Issues concerning the Offshore Loans of Banking Financial Institutions* (《中国人民银行 国家外汇管理局关于银行业金融机构境外贷款业务有关事宜的通知》, “**Circular No.27**”), offshore loans granted by onshore banks shall, in principle, be used for the relevant expenditure within the business scope of the offshore enterprises and the funds shall not be repatriated for use within China through onshore lending, equity investment, or similar arrangements. In practice, most offshore enterprises are not required to specify or publicly disclose a clear business scope under local laws, but often adopt a “general purpose” description. We understand that, in such cases, offshore enterprises borrowing M&A Loans can be deemed within their business scope, and thus generally should not be deemed as violating the restrictions on loan utilization under Circular No.27.

III. Type of M&A Loans: introducing equity participation M&A Loans

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>Article 4 M&A Loans are used to support the onshore acquiring enterprise in achieving actual control, merger, or equity participation in an established and continuously operating target enterprise or asset through means such as acquiring existing equity, subscribing for new equity, acquiring assets, or assuming debts. Based on their purpose, M&A Loans are classified into controlling M&A Loans and equity participation M&A Loans:</p> <p>(1) The controlling M&A Loan refers to a loan supporting a single acquirer or multiple acquiring enterprises acting in concert in obtaining the control rights of the target enterprise or assets.</p> <p>If a single acquirer has already obtained control rights over the target enterprise and intends to maintain or enhance its control rights, it may apply for a controlling M&A Loan when acquiring or subscribing for equity of the target enterprise, provided that the equity ratio acquired in a single transaction shall not be less than 5%.</p> <p>(2) The equity participation M&A Loan refers to a loan supporting a single acquirer in acquiring the equity in the target enterprise but without obtaining control, provided that the equity ratio acquired in a single transaction shall not be less than 20%.</p> <p>If a single acquirer has already held 20% or more of the equity of</p>	<p>Article 4 M&A Loans are used to support the onshore acquiring enterprise in achieving actual control, merger, or equity participation in an established and continuously operating target enterprise or asset through means such as acquiring existing equity, subscribing for new equity, acquiring assets, or assuming debts. Based on their purpose, M&A Loans are classified into controlling M&A Loans and equity participation M&A Loans:</p> <p>(1) The controlling M&A Loan refers to a loan supporting the acquirer in obtaining control rights of the target enterprise or assets.</p> <p>If an acquirer has already obtained control rights over the target enterprise and intends to maintain or enhance its control rights, it may apply for a controlling M&A Loan when acquiring or subscribing for equity of the target enterprise.</p> <p>The acquirer under the preceding paragraph may be a single entity or multiple acquiring enterprises acting in concert.</p> <p>(2) The equity participation M&A Loan refers to a loan supporting a single acquirer in acquiring the equity in the target enterprise but without obtaining control, provided that the equity ratio acquired in a single transaction shall not be less than 20%.</p> <p>If a single acquirer has already held 20% or more of the equity of the target enterprise and intends</p>	<p>Paragraph 1, Article 3 “M&A” under these Guidelines refers to a transaction whereby the onshore acquiring enterprise achieves merger or actual control in an established and continuously operating target enterprise or asset through means such as acquiring existing equity, subscribing for new equity, acquiring assets, or assuming debts.</p> <p>Article 41 These Guidelines shall apply where a commercial bank grants a loan to an onshore acquiring enterprise that has already obtained control rights of the target enterprise and intends to maintain its control rights over the target enterprise, for acquiring or subscribing for the equity of such target enterprise.</p>

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
the target enterprise and intends to further increase its equity ratio without acquiring control, it may apply for an equity participation M&A Loan, provided that the equity ratio to be acquired or subscribed for in a single transaction shall not be less than 5%.	to further increase its equity ratio without acquiring control, it may apply for an equity participation M&A Loan, provided that the equity ratio to be acquired or subscribed for in a single transaction shall not be less than 5%.	

Interpretation: The Official Measures for M&A Loans introduces “equity participation M&A Loans” and distinguishes it from “controlling M&A Loans” as follows:

■ Controlling M&A Loans

- The acquirer under controlling M&A Loans may be “a single entity” or “multiple acquiring enterprises acting in concert”;
- For acquirers who have already obtained control of the target enterprise, the M&A Loan applied for the purpose of acquiring or subscribing for equity of the target enterprise in order to “enhance its control rights” (“**Enhancing Controlling M&A Loans**”), is also included within the scope of controlling M&A Loans. This change addresses the practical needs of some controlling enterprises to further increase their shareholding and aligns with recent market practice;
- Compared to the Draft Measures for M&A Loans, the Official Measures for M&A Loans imposes additional restrictive conditions: (1) under Enhancing Controlling M&A Loans, the equity ratio in the target enterprise acquired in a single transaction shall not be less than 5%; and (2) the acquisition of no less than 5% equity in a single transaction shall be carried out by a “single” acquirer, but not by “multiple acquiring enterprises acting in concert”.

■ Equity Participation M&A Loans

- Banks are permitted to grant equity participation M&A Loans to support equity participation transactions where the acquirer will not get control right as a result of the transaction, provided that equity ratio acquired in a single transaction is not less than 20%; but if the acquirer has already held 20% or more of the equity, subsequent single transactions to increase shareholding shall not be less than 5%;
- Unlike controlling M&A Loans, equity participation M&A Loans are only permitted to be implemented by a single acquirer, but not multiple acquirers/consortia;
- The calculation of equity ratio strictly follows the principle of “shareholding of a single acquirer” and shall exclude the shareholdings of parties acting in concert or affiliates. Multiple equity acquisition transactions shall each meet the minimum equity ratio requirement for a single transaction, and cannot be consolidated to accumulate the already held equity ratio.

It is noteworthy that NFRA Shanghai branch issued the *Pilot Work Plan for Prudently Relaxing Restrictions on Non-Resident M&A Loans in the Lingang Special Area* (the “**Lingang M&A Loan Policy**”, 《在临港新片区审慎放宽非居民并购贷款限制试点工作方案》) on 24 September 2024, which allows eligible banks that have established branches in the Lingang Special Area and conduct business through such branches, to operate non-resident M&A Loans businesses. Such loans may be used to support strategic equity transactions aimed at acquiring partial equity of a target enterprise for strategic investment purposes rather than financial investment purposes. Such strategic equity transactions shall simultaneously satisfy the following conditions: (1) based on horizontal or vertical M&A strategic intent, the acquirer and the target enterprise shall have industrial relevance; (2) the acquirer shall have significant influence over the target enterprise, or be able to jointly control the target enterprise with other parties; and (3) in principle, the cumulative equity acquired in the target enterprise shall not be less than 20%.

IV. Strengthening the Qualification Requirements for Banks

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
Same as the Draft Measures for M&A Loans	<p>Article 5 To commence M&A Loan business, a commercial bank with legal person status shall meet the following conditions:</p> <p>(1) be in sound condition with well-established corporate governance;</p> <p>(2) have a professional team engaged in due diligence and risk assessment of M&A Loans;</p> <p>(3) have a sound regulatory rating in the previous year, and the major regulatory indicators shall meet the regulatory requirements;</p> <p>(4) As of the end of the preceding year, have adjusted consolidated on- and off-balance sheet assets of no less than RMB 50 billion; for conducting equity participation M&A Loan business, such adjusted consolidated on- and off-balance sheet assets as of the end of the previous year shall be no less than RMB 100 billion.</p> <p>Prior to commencing M&A Loan business, the commercial bank</p>	<p>Article 5 To commence M&A Loan business, a commercial bank with legal person status shall meet the following conditions:</p> <p>(1) have a sound risk management and an effective internal control mechanism;</p> <p>(2) have a capital adequacy ratio of not less than 10%;</p> <p>(3) Other regulatory indicators shall meet the regulatory requirements;</p> <p>(4) have a professional team engaged in due diligence and risk assessment of M&A Loans.</p> <p>Prior to commencing M&A Loan business, the commercial bank shall develop the corresponding M&A Loan business process and internal control system, and report the same to the regulatory authorities. After commencing M&A Loan business, if a commercial bank fails to continuously satisfy any of the above conditions, it shall stop conducting new M&A Loan businesses.</p>

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
	shall develop the corresponding business process and internal control system, and file them with NFRA or its local branches.	
Same as the Draft Measures for M&A Loans	Paragraph 2, Article 9 The responsible person of the professional team referred to in the preceding paragraph shall have more than three (3) years of experience in M&A business, and the team members shall include but not be limited to M&A experts, credit experts, industry experts, legal experts and financial experts. The responsible person of the professional team for equity participation M&A Loans shall have more than five (5) years of experience in M&A business.	Paragraph 2, Article 24 The responsible person of the professional team referred to in the preceding paragraph shall have more than three (3) years of experience in M&A business, and the team members shall include but not be limited to M&A experts, credit experts, industry experts, legal experts and financial experts.

Interpretation:

- **Minimum asset threshold:** Paragraph 4 of Article 5 of the Official Measures for M&A Loans, for the first time, sets a hard asset threshold for banks engaging in M&A Loan business i.e., as of the end of the preceding year, a commercial bank with legal person status shall have adjusted consolidated on- and off-balance sheet assets of no less than RMB 50 billion if only engaging in controlling M&A Loan business, or no less than RMB 100 billion if engaging in equity participation M&A Loan business.

Article 32 of the Official Measures for M&A Loans provides that branches of foreign banks shall implement these Measure by reference. However, it remains to be clarified by NFRA whether the branches of foreign banks may include the assets of their parent banks in the calculation to satisfy such requirement.

- **Regulatory rating:** Paragraph 3 of Article 5 of the Official Measures for M&A Loans newly introduces the requirement of sound regulatory rating. However, at present, there is no specific standard for what constitutes a “sound regulatory rating” and local branches of the NFRA may have the discretion in such regard at that time.
- **Professional experience:** Article 9 of the Official Measures for M&A Loans newly requires that, for a bank conducting equity participation M&A Loan business, the responsible person of the professional team shall have more than five (5) years of experience in M&A business.

V. Optimization of Loan Conditions: higher loan ratios and longer loan tenors

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
Same as the Draft Measures for M&A Loans	<p>Paragraph 1, Article 24 Commercial banks shall, comprehensively consider the risks of both the M&A transaction and the M&A Loan, prudently determine the proportion of the M&A loan to the transaction consideration, ensure that M&A funding includes a reasonable proportion of equity capital, and prevent the risks associated with highly leveraged M&A financing.</p> <p>Paragraph 2, Article 24 The proportion of controlling M&A Loan to the M&A transaction consideration shall not exceed 70%, and the proportion of equity capital to the M&A transaction consideration shall not be less than 30%.</p> <p>Paragraph 3, Article 24 The proportion of equity participation M&A Loan to the M&A transaction consideration shall not exceed 60%, and the proportion of equity capital to the M&A transaction consideration shall not be less than 40%.</p>	<p>Paragraph 2, Article 14 Commercial banks shall comprehensively consider the aforesaid risk factors, and, based on the operating and financial conditions of the parties to transactions, as well as the M&A financing method and amount, and other circumstance, reasonably assess the source of repayment of the M&A Loan and prudently determine the financial leverage ratio of the M&A project supported by such M&A Loan, ensure that the sources of M&A funding includes a reasonable proportion of equity capital, and prevent the risks caused by the highly leveraged M&A financing.</p> <p>Article 21 The proportion of the M&A Loan to the M&A transaction consideration shall not exceed 60%.</p>
Same as the Draft Measures for M&A Loans	<p>Article 25 The tenor of a controlling M&A Loan shall in principle, not exceed ten (10) years, and the tenor of an equity participation M&A Loan shall in principle, not exceed seven (7) years.</p>	<p>Article 22 The tenor of an M&A Loan shall generally not exceed seven (7) years.</p>

Interpretation:

■ Changes in major loan conditions:

	The Official Measures for M&A Loans	The 2015 Guidelines
Proportion of M&A Loan to the M&A Transaction Consideration	<ul style="list-style-type: none"> ■ Controlling: ≤ 70% ■ Equity participation: ≤60% 	≤ 60%

	The Official Measures for M&A Loans	The 2015 Guidelines
Tenor	<ul style="list-style-type: none"> ■ Controlling: ≤ ten (10) years ■ Equity participation: ≤ seven (7) years 	≤ seven (7) years
Proportion of equity capital	<ul style="list-style-type: none"> ■ Controlling: ≥ 30% ■ Equity participation: ≥ 40% 	Reasonable proportion

Interpretation:

- **Pilot policies:** On 5 March 2025, a responsible official of the relevant department of NFRA, in response to the Q&A on pilot program for M&A Loans for technology enterprises¹⁰, pointed out that for “controlling” M&A, the pilot program relaxes the cap on the ratio of M&A Loans to the transaction value from “not exceeding 60%” to “not exceeding 80%”, and extends the loan tenor from “generally not exceeding seven (7) years” to “generally not exceeding ten (10) years”. In addition, the Lingang M&A Loan Policy explicitly permits qualified banks that have established branches in the Lingang Special area and conducted business through such branches to carry out pilot non-resident M&A Loan business, raising the proportion of loans to the M&A transaction consideration to 80% and extending the loan tenor to ten (10) years. In accordance with the explanation provided by the responsible official of the relevant department of NFRA in response to the Q&A on the Official Measures for M&A Loans¹¹, after the implementation of the Official Measures for M&A Loans, the aforementioned pilot policies may continue to apply to the relevant enterprises.
- **Scope of equity capital:** The term “equity capital” mentioned in Articles 24 and 27 of the Official Measures for M&A Loans has not been clearly defined. However, based on the funding source requirements imposed by pilot banks on borrowers in the pilot program for M&A Loans for technology enterprises launched in March 2025 - the borrower’s own funds are required to account for no less than 20% of the M&A transaction consideration, and the sources of such funds shall be legal and compliant, not including debt-based funds or other financing instruments that violate regulatory provisions, nor funds that are “equity in form but debt in substance”(名股实债). We understand that “equity capital” stipulated in the Official Measures for M&A Loans shall refer to the acquirer’s own funds, typically corresponding to total owner’s equity in the financial statements, excluding debt-based funds or proceeds from debt financing instruments, or funds that are “equity in form but debt in substance”.

In addition, we believe that the requirements for equity funds in the Official Measures for M&A Loans will not affect the common forms of equity issuance for M&A transactions (such as share roll over (股份上翻), share exchange(换股)) under the 2015 Guidelines in market practice, because the nature of such transactions can be understood as the acquirer using the consideration for issuing or transferring the shares to acquire the target, and from the perspective

¹⁰ <https://www.nfra.gov.cn/cn/view/pages/ItemDetail.html?docId=1200294&itemId=917&generaltype=0>.

¹¹ <https://www.nfra.gov.cn/cn/view/pages/ItemDetail.html?docId=1240856&itemId=915&generaltype=0>.

of the acquirer, the funds received by the acquirer from issuing or transferring the shares belong to self-owned capital/equity funds.

- Calculation of M&A transaction consideration:** Neither the Official Measures for M&A Loans nor the 2015 Guidelines specify how the M&A transaction consideration should be calculated. We understand that the M&A transaction consideration shall cover all the consideration paid for the purpose of the M&A transaction (including the consideration in the form of assumption of debt). Where the acquirer carries out the M&A through a combination of assumption of debt and equity transfer, the M&A transaction consideration shall be determined as the total transaction price before the assumption of such debt. Banks shall comply with the requirements on equity capital and M&A Loan-to-transaction consideration ratios based on such calculation basis.

VI. Entrusted Payment

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>Article 26 Before disbursing the loan, commercial banks shall verify that the borrower has satisfied the conditions to drawdown stipulated in the contract. The conditions to drawdown shall at least include that other M&A transaction funds apart from the M&A Loan, have been fully paid in place in accordance with the agreed payment schedule, and that the compliance conditions for the M&A transaction have been satisfied, among other requirements.</p> <p>Where a borrower applies for an M&A Loan to pay the M&A transaction consideration, the loan shall, in principle, be disbursed through entrusted payment; where entrusted payment is genuinely not feasible, necessary measures shall be taken to ensure that the use of funds is lawful and compliant.</p>	<p>Article 26 Before disbursing the loan, commercial banks shall verify that the borrower has satisfied the conditions to drawdown stipulated in the contract. Where a borrower applies for an M&A Loan to pay the M&A transaction consideration, the loan shall, be disbursed through entrusted payment.</p> <p>The conditions to drawdown shall at least include that other M&A transaction funds apart from the M&A Loan, have been fully paid in place, and that the compliance conditions for the M&A transaction have been satisfied, among other requirements.</p>	<p>Paragraph 1 Article 33 A commercial bank shall specify in a loan contract the conditions to drawdown and the terms concerning payment and utilization of loans. The conditions to drawdown shall at least include that self-raised funds of the acquirer have been fully paid in place, and that the compliance conditions for the M&A have been satisfied, among other requirements.</p>

Interpretation:

- Conditions precedent to drawdown:** Based on the Draft Measures for M&A Loans, the Official Measures for M&A Loans clarifies that for conditions to drawdown, funds for the M&A transaction

are only required to be fully paid in place in accordance with the agreed payment schedule, which means that when a bank disburses an M&A Loan, it is not required that other funds for the M&A transaction have already been fully paid in place; instead, it is sufficient for the corresponding portion of funds to be in place according to the payment schedule agreed between both parties to the M&A transaction.

- Payment management:** The Draft Measures for M&A Loans explicitly required that where a borrower applies for an M&A Loan to pay the M&A transaction consideration, the entrusted payment method shall be adopted. The Official Measures for M&A Loans revises this requirement to provide that the entrusted payment method shall, in principle, be adopted, leaving flexibility for special circumstances where entrusted payment is not feasible, while requiring banks to take necessary measures to ensure the legality and compliance of the funds. When entrusted payment is not adopted, the bank shall assume higher compliance responsibility and prove that the loan funds have not been misappropriated through strengthened internal controls, verification of fund flows and supporting documentation.

VII. Clarifying Restrictions on Rollover of M&A Loans

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>Article 27 Where an M&A Loan is used to roll over the M&A transaction consideration that prepaid by the acquirer, it shall comply with the requirements under these Measures regarding, among others, the minimum proportion of equity capital, and shall not be used to roll over the M&A Loan already obtained. The interval between the first drawdown date of the loan and the completion of full payment of the M&A transaction consideration to be rolled over shall not be more than one (1) year.</p>	<p>Article 27 An M&A Loan may be used to roll over the M&A transaction consideration that has been prepaid by the acquirer, but shall not be used to roll over the M&A Loan already acquired. The interval between the loan processing date and the completion of payment of the M&A transaction consideration to be rolled over shall not be more than one (1) year.</p>	<p>N/A</p>

Interpretation:

- Replacing timing:** The Draft Measures for M&A Loans require that the interval between the loan processing date and the completion of payment of the M&A transaction consideration to be replaced shall not exceed one (1) year. However, the exact timing for “loan processing date” and “completion of payment of the M&A transaction consideration” are not specified. The Official Measures for M&A Loans further clarify that the starting point of the interval shall be the first drawdown date of the M&A Loan, and the ending point shall be the completion of full payment of

the M&A transaction consideration. Where the M&A transaction consideration is paid in stages, the ending point shall be determined by the date on which the final installment of the M&A transaction consideration is paid.

- **M&A transaction consideration to be replaced:** The Official Measures for M&A Loans provide that M&A Loans shall not be used to replace M&A Loans already disbursed, but may be used to replace M&A transaction consideration prepaid by the acquirer. In light of market practice, such prepaid M&A transaction consideration to be replaced may be funded by equity capital or debt-based funds such as bridge loans. Compared to the Draft Measures for M&A Loans, the Official Measures for M&A Loans further clarify that M&A Loans used to replace self-funded M&A transaction consideration are likewise subject to all regulatory requirements, including the minimum proportion of equity capital.

Previously, there were market discussions suggesting that, so long as the aggregate tenor of M&A Loans did not exceed the maximum permitted term (seven (7) years under the 2015 Guidelines), banks could grant M&A Loans to replace M&A Loans already granted by other banks. However, after the Official Measures for M&A Loans take effect, such replacement structure is no longer permissible, thereby eliminating the practice of indefinitely extending loan tenors through “borrowing new loans to repay old ones”.

- **Source of funds for repayment of M&A Loans:** Although Article 27 of the Official Measures for M&A Loans only restricts the use of M&A Loans to replace or repay other M&A Loans, banks are also subject to stringent restrictions on loan purposes, for example, working capital loans shall not be used for equity investment, and fixed asset loans shall be used for the construction, purchase, renovation and other activities of fixed assets during the borrower’s business operation. Accordingly, in replacement scenarios, banks are required to conduct a look-through review of the original purpose of the loan being replaced, so as to avoid using M&A Loans to indirectly circumvent regulatory restrictions applicable to other types of loans. Therefore, in practice, banks usually conduct replacement transactions only within the same loan category and adopt a highly cautious approach to cross-category loan replacements. For M&A Loans, banks generally require that such repayment shall be made only with non-bank loan funds.

VIII. New Concentration Restrictions Imposed on Equity Participation M&A Loans

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>Article 29 The balance of M&A Loans granted by a commercial bank to a single borrower shall not exceed 2.5% of the commercial bank’s net tier 1 capital for the same period.</p> <p>The balance of all M&A Loans granted by a commercial bank shall not exceed 50% of the</p>	<p>Article 29 The balance of all M&A Loans granted by a commercial bank shall not exceed 50% of the commercial bank’s net tier 1 capital for the same period.</p> <p>The balance of equity participation M&A Loans shall not exceed 30% of the balance of</p>	<p>Article 18 The balance of all M&A Loans granted by a commercial bank shall not exceed 50% of the commercial bank’s net tier 1 capital for the same period.</p> <p>Article 20 The balance of M&A Loans granted by a commercial bank to a single borrower shall</p>

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>commercial bank's net tier 1 capital for the same period.</p> <p>The balance of equity participation M&A Loans shall not exceed 30% of the balance of all M&A Loans of a bank.</p>	<p>all M&A Loans of a bank.</p> <p>Paragraph 2, Article 30 The balance of M&A Loans granted by a commercial bank to a single borrower shall not exceed 5% of the commercial bank's net tier 1 capital for the same period.</p>	<p>not exceed 5% of the commercial bank's net tier 1 capital for the same period.</p>

Interpretation: The Official Measures for M&A Loans continue to adopt the regulatory red line on the overall business concentration established in the 2015 Guidelines, expressly providing that the balance of all M&A Loans granted by a commercial bank shall not exceed 50% of the commercial bank's net tier 1 capital for the same period. However, compared to the 2015 Guidelines and the Draft Measures for M&A Loans, the single client concentration requirement has been adjusted and tightened, being reduced from 5% to 2.5%. In addition, a new concentration management requirement for equity participation M&A Loans has been introduced on the basis of the 2015 Guidelines, which provides that the balance of equity participation M&A Loans shall not exceed 30% of the balance of all M&A Loans of a bank.

IX. Strengthening Post-loan Management

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
<p>Article 28 Commercial banks shall strengthen the post-disbursement management of loan funds, timely track the implementation status of M&A transaction, pay close attention to the performance of key terms under the loan contract, monitor the risk factors affecting the borrower's solvency, and strictly prevent the misappropriation of the borrower's funds and affiliated enterprises from extracting loan funds through fraudulent M&A transactions, and other similar acts. Upon discovering any irregularities, the bank shall timely take measures such as requiring additional security, adjusting the loan disbursement conditions or repayment schedule, freezing or</p>	<p>Article 28 Commercial banks shall strengthen the post-disbursement management of loan funds, timely track the implementation status of M&A transaction, pay close attention to the performance of key terms under the loan contract, monitor the risk factors affecting the borrower's solvency, and strictly prevent the misappropriation of the borrower's funds and affiliated enterprises from extracting loan funds through fraudulent M&A transactions, and other similar acts. Upon discovering any irregularities, the bank shall timely take measures such as accelerating loan repayment, requiring additional security, adjusting the loan disbursement conditions or repayment schedule, and</p>	<p>Paragraph 2, Article 33 Commercial banks shall, in accordance with the loan contract, strengthen the management of drawdown and payment of loan funds and monitor the flow of funds, prevent affiliated enterprises from extracting loan funds through fraudulent M&A transactions, and ensure that the loan funds will not be misappropriated.</p> <p>Paragraph 1, Article 35 Commercial banks shall, during the term of the loan, strengthen the post-loan inspection, timely track the implementation status of M&A transaction, regularly evaluate the predictability and stability of the future cash flow of both parties to the M&A transaction, and regularly</p>

The Official Measures for M&A Loans	The Draft Measures for M&A Loans	The 2015 Guidelines
terminating credit facilities, or accelerating loan repayment.	freezing or terminating the credit facilities.	<p>evaluate whether the repayment plan of the borrower matches the repayment source. Where any irregularities arise in the M&A transaction or with either party to the M&A transaction, commercial banks shall timely take effective measures to ensure the safety of the loan.</p> <p>Article 36 Commercial banks shall, during the term of the loan, pay close attention to the performance of key terms under the loan contract.</p>

Interpretation: Compared to the 2015 Guidelines, Article 28 of the Official Measures for M&A Loans requires banks to strengthen post-loan management over borrowers, and further specifies the measures that banks should take to safeguard loan security where risks or irregularities are identified, including requiring additional security, adjusting the loan disbursement conditions or repayment schedule, freezing or terminating credit facilities, accelerating loan repayment, and other measures. Banks may update their M&A Loan contracts as the case may be, to ensure that banks are entitled to take the aforesaid measures for post-loan management purpose.

Transition Period Arrangements

According to the explanation of Q&A¹² given by the responsible person of the relevant department of NFRA regarding the Official Measures for M&A Loans, (1) commercial banks that have already conducted M&A Loan business before the effectiveness of the new measures and still meet the business qualification requirements stipulated in Article 5 of the new measures after their promulgation, may continue their business normally without re-filing; (2) commercial banks that have conducted M&A Loan business before the promulgation of the new measures but do not meet the business qualification requirements under the new measures, shall not engage in M&A loan business after the existing loans naturally run off; (3) for M&A loans where loan contracts have already been signed before the promulgation of the new Measures, banks may perform in accordance with the terms of the contract, and such contracts may be naturally settled upon expiration. If any core terms of the loan contracts need to be amended, we understand banks are required to go through the review and approval procedures according to the Official Measures for M&A Loans to ensure that the amended business complies with the new measures.

¹² <https://www.nfra.gov.cn/cn/view/pages/ItemDetail.html?docId=1240856&itemId=915&generaltype=0>.

5. Draft Amendment – Redrawing the Lines of Banking Supervision in China

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Introduction and Highlights

On December 27, 2025, the Standing Committee of the National People's Congress announced the *Draft Amendment to the Law on the Supervision and Administration of the Banking Industry* (《银行业监督管理法(修订草案)》) (the “**Draft Amendment**”). It makes a comprehensive revision to the existing *Law on the Supervision and Administration of the Banking Industry* (《银行业监督管理法》), enacted in 2003 and amended in 2006 (the “**2006 Law**”), and represents a systemic effort to address the profound changes in the domestic and international environment of the banking sector and the increasing complexity of financial risks.

For banks, the highlights of the Draft Amendment include:

1. **Broadened scope of regulated entities:** the Draft Amendment extends the regulatory umbrella to PRC incorporated financial holding companies, consumer finance companies, and wealth management firms, which could be parents and subsidiaries of banks;
2. **Enhanced supervision of shareholders and actual controllers:** the Draft Amendment introduces “look-through” supervision, bringing major shareholders¹³ and actual controllers of banks under direct regulatory scrutiny of National Financial Regulatory Administration (NFRA);
3. **Supervisors subject to personal accountability:** the Draft Amendment includes supervisors of banks in the scope of personnel subject to accountability, alongside directors and senior management;
4. **Well-established risk resolution framework:** the Draft Amendment sets up a full-process risk resolution framework, covering early rectification, reorganization and takeover of banks under risk;
5. **Forbidden enforcement of foreign discriminatory restrictions:** the Draft Amendment prohibits banks from enforcing or assisting in enforcing foreign discriminatory restrictions (e.g., sanctions) against Chinese persons or entities;
6. **Increased costs for non-compliance:** the Draft Amendment substantially provides higher fines and broader punitive measures at both institutional and individual levels against any violation;
7. **Recovery of remuneration from individuals:** the Draft Amendment empowers NFRA to order a recovery of remuneration from responsible individuals as a new punitive measure; and
8. **Banned cross-border information sharing:** the Draft Amendment prohibits banks from providing

¹³ According to Article 9 of the *Interim Measures for the Equity Management in Commercial Banks*, major shareholders of a commercial bank refer to shareholders who hold or control 5% or more of the shares or voting rights of the commercial bank, or who hold less than 5% of the total capital or total shares but have a significant influence on the operation and management of the commercial bank.

The “**significant influence**” mentioned in the preceding paragraph shall include, but is not limited to, appointing directors, supervisors, or senior management personnel to the commercial bank, influencing the financial and operational management decisions of the commercial bank through agreements or other means, and other circumstances as determined by the China Banking Regulatory Commission or its local offices.

documents or information to foreign regulatory authorities without regulatory consents.

The public consultation period for the Draft Amendment is scheduled from December 27, 2025, to January 25, 2026. The key amendments most relevant to banks are further elaborated in Part II.

Key Amendments

I. Broadened Scope of Regulated Entities

Building on the scope of regulated entities under the 2006 Law, the Draft Amendment expands the coverage to include financial holding companies, auto finance companies, consumer finance companies, money brokerage firms and wealth management companies, while removing urban credit cooperatives from the regulatory scope. Banks should be aware that any of its parent or subsidiaries being one of foresaid regulated entities will be subject to the supervision regime of the Draft Amendment.

2006 Law	Draft Amendment
<p>Paragraph 2 of Article 2 For the purposes of this Law, banking financial institutions refer to financial institutions established within the territory of the People’s Republic of China that take public deposits, such as commercial banks, urban credit cooperatives, and rural credit cooperatives, as well as policy banks.</p>	<p>Paragraph 2 of Article 3 For the purposes of this Law, banking financial institutions refer to financial institutions established within the territory of the People’s Republic of China that take public deposits, such as commercial banks and rural credit cooperatives, as well as policy banks.</p>
<p>Paragraph 3 of Article 2 The supervision and administration of financial asset management companies, trust investment companies, finance companies, financial leasing companies, and other financial institutions established upon the approval of the banking supervision and administration institution of the State Council shall be governed by the provisions of this Law concerning the supervision and administration of banking financial institutions.</p>	<p>Paragraph 3 of Article 3 The supervision and administration of financial holding companies, financial asset management companies, trust companies, enterprise group finance companies, financial leasing companies, auto finance companies, consumer finance companies, money brokerage firms, wealth management companies, and other financial institutions established upon the approval of the banking supervision and administration institution of the State Council shall be governed by the provisions of this Law concerning the supervision and administration of banking financial institutions.</p>

II. Banned Information Provision to Foreign Authorities

Article 8 of the Draft Amendment prohibits banks from providing any file or document related to their business activities to foreign authorities without the consent of NFRA and competent authority(ies) designated by State Council (e.g., People’s Bank of China (PBoC) and Cyberspace Administration of China (CAC)). PBoC has previously provided similar bans with respect to personal financial information and KYC identity and trade information. The Draft Amendment codifies such ban and further expands it to all files and documents related to business activities of banks. Foreign funded banks (including subsidiary banks and foreign bank branches) should be noted that such consent would be required if they provide relevant information or document to offshore parents or affiliates which in turn provide same to foreign authorities.

III. Enhanced Supervision of Shareholders and Actual Controllers

Compared with the 2016 Law, the Draft Amendment introduces new provisions concerning equity management of major shareholders and actual controllers of banks, as well as the controlling shareholders and actual controllers of shareholders of banks, most of which are consistent with the existing regulatory requirements.

2006 Law	Draft Amendment	Implications to Banks
Corporate Compliance Requirements		
/	<p>Article 18 When the banking regulatory authority of the State Council approves the establishment of a banking financial institution, it shall review the following conditions:</p> <p>....</p> <p>(3) The major shareholders and actual controllers shall have sound financial status and a record of integrity, and shall meet the conditions under laws, administrative regulations, and the rules prescribed by the banking regulatory authority of the State Council.</p>	<ul style="list-style-type: none"> ■ The financial and integrity requirements for major shareholders of banks are not new. They have been provided under Article 5 of the <i>Interim Measures for the Equity Management in Commercial Banks</i> (《商业银行股权管理暂行办法》), the “Equity Management Measures”). ■ The financial and integrity requirements for actual controllers of banks are not explicitly provided in existing regulatory framework. The Draft Amendment for the first time

2006 Law	Draft Amendment	Implications to Banks
	...	extends equivalent regulatory requirements to actual controllers of banks.
/	<p>Article 19 The banking regulatory authority under the State Council shall examine and approve the following matters of change for banking financial institutions:</p> <p>...</p> <p>(7) Change of major shareholders or actual controllers;</p> <p>...</p>	<ul style="list-style-type: none"> ■ Article 24(5) of the <i>Commercial Banks Law (2015 Revision)</i> (《商业银行法(2015 修正)》), the “Commercial Banks Law”) only provides that any change in shareholders holding more than five percent (5%) of the total capital or total shareholding of a commercial bank (i.e., major shareholders) shall be subject to approval by NFRA. ■ The Draft Amendment further adds a change in the actual controller of banks as an approval item, while the change in actual controllers (whether the actual controllers of banks or actual controllers of shareholders of banks) is currently not subject to approval by NFRA but only needs to be reported and/or disclosed. Under the current regulatory framework, Article 36 of the Equity Management Measures requires major shareholders of a commercial bank to timely report to the commercial bank any change in their actual controllers; and Article 40 of the Equity Management Measures empowers NFRA to request information on the actual controllers of the shareholders from the bank. Banks are also required under Article 93 of the Corporate Governance Guidelines to disclose

2006 Law	Draft Amendment	Implications to Banks
		the change in the actual controllers of the banks within ten (10) business days of such change.
<p>Article 17 When an application is made to establish a banking financial institution, or when a banking financial institution changes its shareholder who holds more than the prescribed proportion of the total capital or total shares, the banking regulatory authority under the State Council shall examine the shareholder's source of funds, financial status, capital replenishment capability, and integrity status.</p>	<p>Article 21 When an application is made to establish a banking financial institution, or when a banking financial institution changes its major shareholder or actual controller, the banking regulatory authority under the State Council shall examine the major shareholder' and actual controller' source of funds, financial status, capital replenishment capability, equity structure, and integrity status.</p> <p>The major shareholder of the banking financial institution, and the controlling shareholder and actual controller of such major shareholders who are subject to examination in accordance with the preceding paragraph shall also meet the conditions stipulated by laws, administrative regulations, the State Council, and the banking regulatory authority under the State Council.</p>	<ul style="list-style-type: none"> ■ The 2016 Law focused on major shareholders while the Draft Amendment further brings actual controllers under direct regulatory scrutiny. The Draft Amendment also extends compliance obligations to the controlling shareholders and actual controllers of major shareholders of the banks. This aligns with Article 40 of the Equity Management Measures, which mandates NFRA to conduct look-through supervision on major shareholders alongside their affiliates, parties acting in concert, and ultimate beneficial owners.
/	<p>Article 27 Shareholders of a banking financial institution shall perform their capital contribution obligations in accordance with the law, using their own funds for capital contribution, unless otherwise stipulated by the state. No entity or individual shall, in violation of regulations, entrust others to hold or accept entrustment from others to hold equity in a banking financial institution.</p>	This is not a new requirement. Similar requirements have been provided in Articles 10 and 12 of the Equity Management Measures, Article 16(1) of the <i>Corporate Governance Guidelines for Banking and Insurance Institutions</i> (《银行保险机构公司治理准则》), the “ Corporate Governance Guidelines ”), and Article 7 of the <i>Measures for the Supervision of the Conduct of</i>

2006 Law	Draft Amendment	Implications to Banks
		<p><i>Major Shareholders of Banking and Insurance Institutions (Trial)</i>(《银行保险机构大股东行为监管办法(试行)》), the “Supervision Measures of Major Shareholders”), which require shareholders to make capital contributions using their own funds and forbid entrusted or nominee shareholding arrangements.</p>
/	<p>Article 28 The major shareholders of a banking financial institution shall, in accordance with the relevant regulations, disclose to the banking financial institution, layer by layer, their shareholding structure up to the actual controller, as well as their affiliated relationships with other shareholders. They shall report any information regarding themselves, their controlling shareholders, actual controllers, or related parties that may affect the qualification of shareholders or result in changes to the shareholding structure of the banking financial institution, in a timely, accurate, and complete manner. The specific measures for administration shall be formulated by the banking regulatory authority of the State Council.</p>	<p>These look-through equity management requirements align with Articles 12 and 36 of the Equity Management Measures, Article 16(3) of the Corporate Governance Guidelines and Article 8 of the Supervision Measures of Major Shareholders.</p>
/	<p>Article 29 The shareholders and actual controllers of a banking financial institution shall not engage in the following acts:</p> <p>(1) Interfering with the management and operation of the banking financial institution in</p>	<ul style="list-style-type: none"> ■ Under the current regulatory framework, several different rules provide for the negative list governing the conduct of major shareholders of banks, controlling shareholders and actual controllers of major

2006 Law	Draft Amendment	Implications to Banks
	<p>violation of regulations;</p> <p>(2) Illegally occupying or appropriating the assets of the banking financial institution, or the funds of depositors and other clients;</p> <p>(3) Conducting related-party transactions with the banking financial institution in violation of regulations;</p> <p>(4) Making false contributions or withdrawing contributions improperly;</p> <p>(5) Transferring or pledging equity in violation of regulations;</p> <p>(6) Engaging in other acts in violation of laws, administrative regulations, or the rules prescribed by the banking regulatory authority of the State Council.</p> <p>The controlling shareholders and actual controllers of the major shareholders of a banking financial institution shall also not engage in any of the acts listed above.</p> <p>Banking financial institutions and their employees shall not assist the shareholders, actual controllers, or the controlling shareholders and actual controllers of major shareholders in engaging in the acts specified in the preceding two paragraphs.</p>	<p>shareholders of banks, and/or controlling shareholders and actual controllers of banks with varying degrees and with different focuses, such as Articles 18, 21, 22 and 23 of the Equity Management Measures, Article 14 of the Supervision Measures of Major Shareholders, Article 16 of the Corporate Governance Guidelines, and other related rules. The Draft Amendment introduces a unified negative list that equally applies to shareholders and actual controllers of banks, as well as the controlling shareholder and actual controller of each major shareholder of the bank.</p> <p>■ In addition, the Draft Amendment emphasizes that employees of banks shall not assist the aforementioned entities or persons to commit any violation, such as interfering with management or misappropriating funds.</p>
Reporting and Information Disclosure		

2006 Law	Draft Amendment	Implications to Banks
<p>Article 33 For the purpose of performing its regulatory functions, the banking regulatory authority shall have the power to require banking financial institutions to submit, in accordance with relevant regulations, balance sheets, profit and loss statements and other materials related financial accounting, statistical statements and operational and management, as well as audit reports issued by certified public accountants.</p>	<p>Paragraph 1 of Article 45 For the purpose of performing its regulatory functions, the banking regulatory authority shall have the power to require banking financial institutions to submit, in accordance with relevant regulations, financial accounting reports, statistical statements, and other documents and materials related to business operations and management. It may also require the major shareholders and actual controllers of banking financial institutions to provide relevant documents and materials within a specified time limit.</p> <p>Documents and materials submitted or provided by banking financial institutions and their major shareholders and actual controllers to the banking regulatory authority shall be true, accurate, and complete.</p>	<p>Compared with the 2006 Law, the reporting obligations have been expanded from banks to their major shareholders and actual controllers. This should not cause additional reporting obligations for major shareholders of banks, as Article 40 of the Equity Management Measures already requires all shareholders of banks to report relevant information as required by NFRA, but the actual controllers of banks are not subject to express reporting obligations under the current regulatory framework.</p>
<p>Article 36 The banking regulatory authority shall order banking financial institutions to truthfully disclose to the public, in accordance with regulations, their financial and accounting reports, risk management status, changes in directors and senior management personnel, and other material matters.</p>	<p>Article 50 Banking financial institutions shall, in accordance with regulations, truthfully disclose to the public their financial and accounting reports, risk management status, equity and related-party transaction information, changes in directors, supervisors, and senior management personnel, and other material matters.</p> <p>The major shareholders and actual controllers of banking financial institutions shall cooperate with the banking financial institutions in fulfilling the</p>	<ul style="list-style-type: none"> Compared with the 2006 Law, the Draft Amendment expands the scope of disclosure to include equity structures, related-party transactions, and change in supervisors. However, these requirements are not new as they have been provided under existing rules, such as the Equity Management Measures and the <i>Information Disclosure Measures for Commercial Banks</i> (《商业银行信息披露办法》).

2006 Law	Draft Amendment	Implications to Banks
	<p>information disclosure obligations stipulated in the preceding paragraph.</p>	<ul style="list-style-type: none"> ■ The Draft Amendment further adds that major shareholders and actual controllers of banks shall cooperate with banks on information disclosure, which is not new for major shareholders and those actual controllers of banks which are also actual controllers of bank shareholders, as similar requirement has been provided under Article 48 of the Equity Management Measures.
Regulatory Measures		
<p>Article 35 The banking regulatory authority may, in light of the needs of performing its duties, conduct regulatory talks with the directors and senior management personnel of banking financial institutions, and require them to make explanations on the major matters concerning the business activities and risk management of such institutions.</p>	<p>Article 49 In order to guard against risks and maintain market order, the banking regulatory authority may take measures such as issuing risk warnings, putting forward regulatory opinions, and conducting regulatory talks against banking financial institutions as well as their directors, supervisors, senior management personnel, major shareholders, actual controllers, and other relevant personnel.</p>	<p>Under the 2006 Law, NFRA may take regulatory measures against directors and senior management, while the Draft Amendment empowers NFRA to adopt wider regulatory measures against banks and additional persons, including supervisors, major shareholders, actual controllers, and other relevant personnel. The scope of “other relevant personnel” is not clearly defined, but it is likely that business head, key persons of specific business or anyone else who takes direct responsibility would be deemed relevant personnel.</p>
<p>Article 37 Where a banking financial institution violates the rules of prudent operation, the banking regulatory authority under the State Council or its provincial-level dispatched office shall order it to make corrections within a prescribed period. If</p>	<p>Article 51 Where a banking financial institution violates the rules of prudent operation, the banking regulatory authority under the State Council or its provincial-level dispatched office shall order it to make corrections within a prescribed period. If</p>	<ul style="list-style-type: none"> ■ The Draft Amendment empowers NFRA to take more regulatory measures against violations, such as restricting banks from paying remuneration to directors, supervisors and senior management personnel; restricting

2006 Law	Draft Amendment	Implications to Banks
<p>such institution fails to make corrections by the deadline, or if its conduct seriously endangers its sound operation or harms the legitimate rights and interests of depositors and other customers, the following measures may be taken, depending on the circumstances, upon approval by the person in charge of the banking regulatory authority under the State Council or its provincial-level dispatched office:</p> <ol style="list-style-type: none"> (1) Order the suspension of certain business activities and cease the approval of new business operations; (2) Restrict the distribution of dividends and other income; (3) Restrict the transfer of assets; (4) Order the controlling shareholder to transfer its equity or restrict the rights of relevant shareholders; (5) Order the replacement of directors or senior management personnel, or restrict their rights; (6) Cease the approval for establishing new branches. <p>After rectification, the banking financial institution shall submit a report to the banking regulatory authority under the State Council or its provincial-level dispatched office. If, upon inspection and acceptance, the institution is found to be in</p>	<p>such institution fails to make corrections by the deadline, or if its conduct seriously endangers its sound operation or harms the legitimate rights and interests of depositors and other customers, the following measures may be taken, depending on the circumstances, upon approval by the person in charge of the banking regulatory authority under the State Council or its provincial-level dispatched office:</p> <ol style="list-style-type: none"> (1) Restrict or suspend certain business activities, cease the approval of new business operations, and cease the approval for establishing new branches; (2) Restrict the distribution of or restrict the distribution of dividends to relevant shareholders, and restrict the payment of remuneration and provision of benefits to directors, supervisors, and senior management personnel; (3) Restrict the transfer of assets, significant expenditures, or the creation of other rights on assets; (4) Order the transfer of assets or business; (5) Order major shareholders to replenish capital within a prescribed period in accordance with regulations; (6) Order the responsible shareholders or actual controllers to transfer their equity or shift actual 	<p>banks from making major expenses or creating any rights over assets, ordering banks to transfer assets or business, ordering major shareholders to supplement capital, ordering responsible shareholders or actual controllers to transfer equity or actual control or restricting their rights, etc.</p> <ul style="list-style-type: none"> ■ Notably, while the 2006 Law primarily targeted institutional-level violations, the Draft Amendment expands its regulatory radar to all shareholders and actual controllers of banks, which, if found to abuse their rights and violate the Draft Amendment, can be the subject of regulatory measures taken by NFRA.

2006 Law	Draft Amendment	Implications to Banks
<p>compliance with the relevant rules of prudent operation, the relevant measures specified in the preceding paragraph shall be lifted within three days from the date of completion of the inspection.</p>	<p>control within a prescribed period, or restrict their rights;</p> <p>(7) Order the replacement of directors, supervisors, or senior management personnel, or restrict their rights;</p> <p>(8) Other measures as stipulated by laws and administrative regulations.</p> <p>Where the shareholders or actual controllers of a banking financial institution abuse their shareholder rights or control, thereby harming the legitimate rights and interests of the banking financial institution, depositors, and other customers, the banking regulatory authority under the State Council or its provincial-level dispatched office shall order them to make corrections within a prescribed period. If they fail to make corrections by the deadline or if the circumstances are serious, the measures specified in the first paragraph may be taken, depending on the circumstances, and they may be prohibited from investing in banking financial institutions again.</p> <p>After rectification, the banking financial institution or its relevant shareholders or actual controllers shall submit a report to the banking regulatory authority under the State Council or its provincial-level dispatched office. If, upon inspection and acceptance, the institution is found to have met the corresponding rectification requirements, the</p>	

2006 Law	Draft Amendment	Implications to Banks
	<p>relevant measures specified in the preceding two paragraphs shall be lifted within three days from the date of completion of the inspection.</p>	
<p>Article 40 Where a banking financial institution is placed under take-over, restructuring, or is revoked, the banking regulatory authority under the State Council has the power to require the directors, senior management personnel, and other employees of said institution to perform their duties in accordance with the requirements of the banking regulatory authority.</p> <p>During the period of take-over, restructuring, or liquidation upon revocation, the following measures may be taken against the directly responsible directors, senior management, and other directly responsible personnel, subject to the approval of the responsible person of the banking regulatory authority under the State Council:</p> <p>(1) Where the departure of directly responsible directors, senior management, or other directly responsible personnel from the country will cause significant loss to national interests, notice shall be sent to the exit control</p>	<p>Article 63 Where a banking financial institution encounters major risks, the banking regulatory authority under the State Council has the power to require the directors, supervisors, senior management personnel, and other employees of said institution to perform their duties, in accordance with the requirements of the banking regulatory authority under the State Council.</p> <p>Subject to the approval of the responsible person of the banking regulatory authority under the State Council, the following measures may be taken against the directly responsible directors, supervisors, senior management, and other directly responsible personnel, as well as shareholders, actual controllers, and other institutions and personnel suspected of violating the law:</p> <p>(1) Where their departure from the country will cause significant loss to national interests, notice shall be sent to the immigration</p>	<p>The Draft Amendment significantly enhances regulatory intervention capabilities and broadens the scope of personal accountability compared to the 2006 Law:</p> <ul style="list-style-type: none"> ■ Regarding the timing of intervention, the 2006 Law permits NFRA to step in during the take-over, restructuring, or liquidation of a bank, while the Draft Amendment permits the regulatory intervention as early as a major risk arises to a bank. ■ In terms of the personnel subject to restrictive measures, the 2006 Law primarily targets directors, senior management, and other directly responsible personnel. The Draft Amendment additionally subject supervisors, shareholders, actual controllers, and other institutions or personnel suspected of violating the law to the same restrictive measures.

2006 Law	Draft Amendment	Implications to Banks
<p>authorities to block their departure in accordance with the law;</p> <p>(2) Apply to the judicial authorities to prohibit them from moving or transferring property, or from creating other rights over their property.</p>	<p>management authorities to block their departure in accordance with the law;</p> <p>(2) Apply to the judicial authorities to prohibit them from moving or transferring property, or from creating other rights over their property.</p>	

IV. Overall Equity Investment Approval System to be Established

Article 43 of the Commercial Banks Law provides that banks shall not invest in any non-banking financial institutions or enterprises, unless otherwise stipulated by the state. Articles 20 and 25 of the Draft Amendment provides that NFRA shall formulate detailed rules on the equity investment by banks. Currently, NFRA has formulated relevant administrative approval guidelines for banks to invest in or establish domestic or overseas financial institutions, but there are no clear unified rules governing the investment in non-financial institutions. The changes in the Draft Amendment may indicate an overall equity management approval system applicable to domestic and overseas equity investment by banks will be rolled out after the Draft Amendment takes into effect.

V. Strengthened Rule of Conduct of Employees

Article 30 of the Draft Amendment, for the first time, introduces a dedicated provision setting out requirements for the conduct, professional competence, and ethical standards of employees in banks.

In addition to the prohibited conduct of employees mentioned in paragraph 3 of Article 29, Article 31 further specifies following prohibited conduct for banks and their employees: (1) funneling benefits through related-party transactions; (2) failing to fulfill due diligence and risk management obligations in lending and other business activities; (3) conducting business in violation of, or by circumventing, regulatory indicators and classification requirements; (4) using false or misleading advertising to defraud depositors and other customers. (5) infringing upon the legal rights of customers through illegal fees or the withholding of funds; (6) disclosing, selling, or illegally providing others with state secrets, work secrets, trade secrets, or personal information of depositors and customers obtained during business; and any other acts that seriously violate the rules of prudential operation.

VI. Forbidden Enforcement of Foreign Discriminatory Restrictions

Article 44 of the Draft Amendment explicitly prohibits banks from enforcing or assisting in enforcing discriminatory restrictions imposed by foreign countries against Chinese citizens, legal persons and other organizations. This echoes the existing regulatory requirement under Article 12 of the *Anti-foreign Sanctions Law* (《反外国制裁法》). Banks should take caution when it comes to dealing with clients subject to foreign sanctions to avoid potential non-compliance with PRC laws or give rise to claims from injured parties.

VII. Well-established Risk Resolution Framework

The Draft Amendment sets up a full-process risk resolution mechanism for banks, covering early rectification, reorganization, and takeover, and clearly defines the applicable conditions, procedures, and time limits for each risk resolution.

Specifically, Article 54 introduces statutory procedures for early correction and comprehensive risk resolution in case of risk hazards (风险隐患) identified with respect to any bank. Article 55 permits NFRA to appoint a rectification team to monitor the bank's operation and management activities for a six-month period if such bank is found to have major risk hazards (重大风险隐患) such as deterioration in operation and management, severe disorder in corporate governance, etc. Where such bank fails to resume normal operation upon the expiry of the rectification period, NFRA shall be able to take, or

facilitate the taking of, measures such as reorganization, takeover, license cancellation and bankruptcy. Therefore, after the enactment of the Draft Amendment, NFRA will be empowered to step in the management of banks as early as any risk hazard is identified before the reorganization and takeover take place.

VIII. Enhanced Legal Accountability and Increased Penalties

The Draft Amendment significantly overhauls the chapter on legal liabilities (Articles 65-76), addressing the limited punitive power under the 2006 Law by substantially increasing the cost of non-compliance and broadening the scope of accountability. Key revisions include:

1. **Expanded Scope of Institutional Liability:** Article 68 of the Draft Amendment define the following acts as violations for which banks may be penalized:
 - (a) Banks provide documents or information to foreign regulatory authorities without required consents.
 - (b) Directors or senior management of banks perform their duties without obtaining the required qualifications.
 - (c) Banks fail to suspend or terminate cooperation with relevant banking service institutions as required by NFRA.
2. **Expanded Scope of Individual Liability:** According to Article 70 of the Draft Amendment, supervisors are additionally included among those subject to accountability, alongside directors, senior management personnel, and other responsible persons.

Besides existing penalties such as high fines, disqualification from holding office, and lifetime bans in the banking sector, NFRA may order banks to recover remuneration from the accountable individuals as an additional punitive measure.

3. **Legal Liabilities of Shareholders and Actual Controllers:** Articles 69 and 71 of the Draft Amendment focus on the legal liabilities of shareholders and actual controllers of banks as following:

Violations	Penalties
Failure by banks, major shareholders, or actual controllers of the banks to submit reports, statements, or required data.	Ordered to rectify; failure to rectify within the prescribed time limit or serious circumstances may result in a fine ranging from RMB 200,000 to RMB 2,000,000.
(1) Becoming major shareholders or actual controller of banks without regulatory approval; (2) Failing to fulfill capital contribution obligations as shareholders of banks; (3) Illegally entrusting others, or accepting entrustments, to hold equity in a bank; (4) Major shareholders of banks failing to report equity-related information as required under	<ul style="list-style-type: none"> ■ Ordered to rectify; illegal gains shall be confiscated, and a fine of one to ten times the amount of the illegal gains may be imposed. Where there are no illegal gains or the illegal gains are less than RMB 500,000, a fine ranging from RMB 500,000 to RMB 5,000,000 may be imposed. ■ Where the circumstances are serious or rectification is not made within the prescribed

Violations	Penalties
<p>Article 28 of the Draft Amendment;</p> <p>(5) Banks, their shareholders and actual controllers, as well as the controlling shareholders and actual controllers of major shareholders, engaging in any prohibited conduct listed in the negative list under Article 29 of the Draft Amendment;</p> <p>(6) Failing to cooperate with the bank in fulfilling prescribed information disclosure obligations;</p> <p>(7) Major shareholders or actual controller of banks refusing to comply with regulatory measures under Article 51 of the Draft Amendment.</p>	<p>time limit, the relevant shareholders may be ordered to return dividends distributed within a specified period.</p> <ul style="list-style-type: none"> ■ Responsible officers and other directly responsible personnel may be given a warning and fined RMB 50,000 to RMB 500,000.

4. **New Penalties for Employees:** According to Article 74 of the Draft Amendment, NFRA may issue warnings and impose fines ranging from RMB 50,000 to RMB 500,000 on bank employees who violate the law. For severe violations, NFRA may revoke the qualifications of directly responsible directors and senior management for a specified period or permanently, and may prohibit relevant responsible personnel from engaging in banking activities for a specified period or permanently.

Conclusion

The Draft Amendment represents a fundamental overhaul of China’s banking supervision law. It signals a clear regulatory intent to move towards a more comprehensive, penetrating, and stringent supervisory regime. The focus on shareholder and actual controller accountability, employee conduct, systemic risk disposal, and restrictions on information provision to foreign authorities will necessitate a thorough review and potential adjustment of internal governance, compliance, and risk management frameworks within banks.

Important Announcement

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