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1. The Regulatory Data Protection System Takes Effect, Injecting New Vitality into Innovative Drug Transactions – An Analysis of the Implementation Measures for Regulatory Data Protection

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On March 19, 2025, the General Affairs Department of the National Medical Products Administration ("**NMPA**") issued the *Implementation Measures for Regulatory Data Protection (Trial, Draft for Comments)* (the "**Draft for Comments**") and the *Working Procedures for Regulatory Data Protection (Draft for Comments)* to further advance the implementation of the Regulatory Data Protection system (the "**RDP System**")(For an analysis of these two documents, please refer to our previously published article: *A New Perspective on Innovative Drug Transactions: Analysis of the New Draft of the Regulatory Data Protection System (Bilingual)*).

On May 15, 2026, the NMPA released the official version of the *Implementation Measures for Regulatory Data Protection* (the "**Measures**") and its supporting *Working Procedures for Regulatory Data Protection*. The final *Measures* made several adjustments to the *Draft for Comments*, demonstrating the regulators' commitment to fostering innovation by extending data protection periods for various categories of drugs. The *Measures* mark the formal implementation of the RDP System, adding an important administrative protection tool for innovative drugs and significantly benefiting the innovative drug transaction ecosystem across multiple dimensions. Transacting parties should pay close attention to the implications of this new system and adjust their transaction structures based on actual needs. This article provides an overview of the RDP System, highlights key changes between the *Measures* and the *Draft for Comments*, and specifically analyzes the impact of the RDP system on innovative drug transactions for the reference of all stakeholders.

Overview of the RDP System

I. Concept of the RDP System

The RDP System is an administrative mechanism for drug protection that operates independently of the patent system. Under this system, drug regulatory authorities grant exclusive protection for a specified period to trial data submitted by innovative or first-generic drug companies. During this data protection period, no other applicant may rely on such protected data to apply for marketing approvals or supplemental approvals without the data holder's consent.

A core condition for trial data to qualify for data protection is that such data must be original trial data proving safety and efficacy. Data that do not generate new evidence on safety or efficacy – such as bioavailability, bioequivalence, and vaccine immunogenicity data – are explicitly excluded from protection. Similarly, clinical changes such as new indications, new patient populations, or

[1] Yixi Zhao has contributions to this article.

combination therapies must generate new and sufficient trial data demonstrating safety and efficacy to qualify for new data protection.

The specific data eligible for protection are trial data that are submitted in marketing authorization applications for qualifying chemical drugs and biological products, independently generated by the applicant, undisclosed, and otherwise eligible for protection. The scope of data includes but is not limited to: pharmaceutical data such as drug substance and product research, manufacturing processes, quality standards, stability, and packaging compatibility; non-clinical data such as pharmacodynamics, pharmacokinetics, toxicology, and safety pharmacology; and clinical data from early-phase (Phase I/II) and pivotal (Phase III) clinical trials.

II. Effects of the RDP System

The RDP System serves as a shot in the arm for the pharmaceutical R&D and innovation industry. For new drugs, including innovative and improved drugs, it guarantees a data protection period of at least 4 to 6 years, which can delay generic entry even if patents expire early or are invalidated, ensuring stable revenue expectations post-launch. For first generics that fill domestic clinical gaps, a 3-year data protection period is granted to secure a reasonable first-mover advantage and return on investment, encouraging the expedited launch of generics that address unmet clinical needs in China.

On the other hand, data protection is a double-edged sword, as it may delays the market entry of generics to some extent, temporarily lowering drug accessibility and increasing public healthcare costs. Having undergone years of deliberation since its first appearance in the *Regulations for the Implementation of the Drug Administration Law (2002)*, the final implementation of RDP system reflects a resolute policy commitment at the national level to support Chinese innovative drug industry despite competing priorities, promising profound long-term benefits for the sector's development.

III. Alignment Between RDP system and Patent Linkage system

Both the patent linkage system and the RDP System function as pre-market review procedures for generic drugs, leading to certain procedural overlaps. Prior to the implementation of the RDP System, generic applicants could file for marketing approval at any time alongside a patent declaration, and launch immediately upon a successful patent challenge or non-infringement ruling. Under the RDP System, however, the regulations do not explicitly clarify the earliest date a generic applicant can file a patent declaration. Given that patent declarations must accompany marketing applications, and Article 12 of the *Measures* states that "after a drug obtains data protection, other applicants may submit marketing applications relying on the protected data within 1 year prior to the expiration of the data protection period" – we understand that generic patent challenges will be constrained by the data protection timeline. Consequently, patent declarations can be filed no earlier than one year before the data protection period expires. Compared to the US system, China does not grant generic applicants who file Paragraph IV certifications the opportunity to submit their marketing applications one year earlier than other generic competitors, further demonstrating China's commitment to fostering the development of innovative drugs.

Key Modifications in the Measures in view of the Draft for Comments

I. Eliminating Deduction Formula for Drugs Approved Abroad but Not in China, and Extending Data Protection for Multiple Drug Categories

Compared with the *Draft for Comments*, the data protection period remains unchanged at 6 years for Category 1 innovative drugs and Category 5.1 innovative drugs, and at 3 years for qualifying first generics. Protection periods for other drug categories have been extended. Notably, the protection for improved drugs has been increased from 3 to 4 years. Furthermore, the *Measures* eliminated the complex calculation formula previously applied to innovative and improved drugs that were "approved abroad but not yet in China". Instead, a full, unreduced protection period of 6 or 4 years applies directly, without deducting the time gap between the overseas approval date and the domestic application acceptance date.

While the formula was originally designed to incentivize overseas drugs to enter the Chinese market rapidly, drug delays are in fact often caused by objective R&D hurdles or regulatory backlogs rather than a lack of commercial willingness. Eliminating this formula simplifies the application and administrative approval processes for applicants. More importantly, it significantly extends the data protection periods for those drugs, fully acknowledging the value of trial data and innovation, and reinforcing a policy direction that encourages foreign innovative drugs and first generics into China.

II. Extending Data Protection from 4 to 6 Years for Global New Indications of Drugs with Active Ingredients Approved Abroad but Not in China

The *Measures* introduced a major new provision: for drugs whose active ingredients are marketed abroad but not yet in China, if the applicant applies directly in China for a global new indication (rather than an indication already approved overseas), the drug will enjoy a 6-year data protection period instead of the standard 4-year period for improved drugs, even though it remains classified as a Category 2.4 improved drug.

This new provision addresses an inversion in the initial framework design of the *Draft for Comments*. Without this clause, if an innovative liver cancer drug already marketed in the US were filed in China for liver cancer, it would receive 6 years of protection. However, if the same drug were filed in China for a global new indication such as gastric cancer, its protection would shrink to 4 years due to its Category 2.4 classification. This created an illogical scenario where higher innovation resulted in a downgraded protection period.

From an R&D perspective, developing a global new indication means that companies cannot rely on pre-existing overseas clinical conclusions; they must conduct a full suite of high-standard clinical trials. The associated scientific risks, financial investments, and stringent regulatory demands are essentially identical to those of a Category 1 innovative drug or a Category 5.1 innovative drug. By leveling the protection period up to 6 years, the *Measures* align R&D risks with reward expectations more equitably, encouraging multinational pharma companies to strategically prioritize China as a debut site for global new indications.

III. A 4-Year Data Protection Period Applies to New Indications for Drugs Whose Active Ingredients Are Already Marketed Domestically

Building upon the aforementioned clause, the *Measures* emphasize that for drugs whose active ingredients have already been approved in China, any subsequent new indications (even for a global new indication) are ineligible for the 6-year term and will receive a 4-year data protection period. The rationale is that since the active ingredient is already approved domestically, the sponsor only needs to submit supplemental clinical data required for that specific new indication. The overall trial costs and data volume are significantly lower than those required for full-scale new drug development. Consequently, aligning them with standard improved drugs under a 4-year protection tier is more scientifically and economically sound.

Impact on Innovative Drug Transactions

I. Generating Higher Potential Revenues for Innovative Drugs

The RDP System will strengthen the market exclusivity of innovative drugs, effectively softening the impact of the "patent cliff". It can substantially prolong market exclusivity for drugs with short patent lives and mitigate the risk of losing protection for drugs if its patents are invalidated early, thereby significantly boosting pipeline valuations. With more stable expectations, potentially longer exclusivity, and higher pipeline values, companies are well-positioned to negotiate more favorable upfront payments, milestone schedules, and royalty percentages.

Among various financial terms, the implementation of the system is poised to specifically optimize royalty structures. First, the Royalty Term is typically defined by the latest of three dates: the expiration of the last valid patent claim, a specified period post-first commercial sale, or the expiration of all regulatory exclusivities (which typically refers to the RDP period). Since RDP can last up to 6 years for innovative drugs, compared to before when RDP was unavailable, now RDP may potentially prolong the Royalty Term, depending on the negotiations between the parties. Furthermore, license agreements commonly include a royalty step-down clause (where the royalty rate is slashed or halved once a generic enters the market). By delaying generic entry, RDP postpones this rate reduction, ensuring that licensors can maintain high royalty rates for a longer period and increase the total revenue.

Under RDP, generic competitors cannot use the innovator's data to apply for approval during the data protection period without authorization from the data holder. This allows the data holder to license "early data access", permitting generics to rely on the data package to for market application ahead of the RDP expiration in exchange for financial benefits.

II. Providing Greater Strategic Flexibility for Drug Launch Planning

Compared to the *Draft for Comments*, the *Measures* no longer deduct the time difference between overseas approval and domestic application acceptance for innovative and improved drugs approved abroad but not yet in China. This allows for a much more flexible and relaxed timeline between overseas and domestic drug launches.

At the same time, companies must note that a new drug's first indication in China receives 6 years of data protection, whereas subsequent indications receive only 4 years. Consequently, during drug development, regulatory filings, and transaction negotiations, parties can strategically select which indication to launch first in China to lock in the maximum 6-year protection window, thereby maximizing mutual commercial interests.

Overall, the implementation of the RDP System will inject fresh vitality into innovative drug transactions, encourage overseas biotechs to enter the Chinese market, drive high-quality innovation in China's life sciences industry, and ultimately benefit the patients.

2. China's HGR Draft Rules Signal Regulatory Easing: Key Takeaways from the Implementing Rules for the Administrative Regulation on Human Genetic Resources (Draft for Comments)

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On May 8, 2026, the National Health Commission ("**NHC**") released the *Implementing Rules for the Administrative Regulation on Human Genetic Resources (Draft for Comments)* ("**Draft for Comments**"), proposing amendments to the current *Implementing Rules for the Administrative Regulation on Human Genetic Resources* ("**Current Implementing Rules**") formulated by the Ministry of Science and Technology ("**MOST**") in 2023 (for our interpretation of the Current Implementing Rules, please see our previous article: *Han Kun Perspective | First Release: Key Takeaways from the Implementing Rules for the Administrative Regulation on Human Genetic Resources*), and is soliciting public comments.

The amendment is not merely a technical carryover of rules following the transfer of regulatory authority over human genetic resources ("**HGR**") management from MOST to the NHC (for our interpretation of the change in HGR regulatory authority, please see our previous article: *Han Kun Quick Comments | Further Amendments to the Regulations on the Administration of Human Genetic Resources*). Rather, guided by the regulatory principle of "strictly regulating what should be regulated while easing restrictions where appropriate", the Draft for Comments introduces a number of new regulatory mechanisms and requirements. Overall, while preserving the fundamental regulatory framework and security baseline for HGR regulation in China, the Draft for Comments reflects, as compared with the Current Implementing Rules, a trend toward greater facilitation, precision, and regulatory flexibility in areas including filings for international cooperative clinical trials, determination of foreign entities, scope of HGR collection approvals, external provision of HGR information in academic contexts, special procedures involving Hong Kong and Macau institutions, and integration with the administrative penalty procedures.

Drawing on the Current Implementing Rules and practical experience, this article analyzes several proposed amendments in the Draft for Comments that may materially affect pharmaceutical companies, medical institutions, research institutions, and related investors, for industry reference and discussion.

Accelerated Filing for International Cooperative Clinical Trials: Introduction of Same-Day Confirmation for "No Cross-Border Information Transfer"

While retaining the filing mechanism for international cooperative clinical trials, the Draft for Comments further establishes an expedited confirmation mechanism for filings that do not involve cross-border transfer of HGR information. Under the current HGR regulatory framework, international cooperative clinical trials conducted for obtaining marketing authorization for drugs or medical devices in China are subject to a filing regime, provided that no HGR materials are transferred abroad, the relevant HGR are collected within qualified clinical medical institutions, and testing, analysis, and disposal of remaining materials are conducted within such institutions or domestic entities designated in the clinical trial protocol.

[2] Yixi Zhao has contributions to this article.

Such international cooperative clinical trials must be filed with the NHC prior to commencement. Building on this existing filing mechanism, the Draft for Comments introduces a same-day confirmation mechanism for filings that do not involve cross-border transfer of HGR information. Specifically, where the filing does not involve cross-border transfer of HGR information, the NHC shall, in principle, confirm the filing on the same working day as receipt of the application; where the application is received after working hours or during statutory holidays, confirmation shall be completed on the next working day.

Under the current HGR regulatory framework, regulation of HGR information is generally described in terms of "providing" or "opening access to" it for foreign entities or overseas individuals. The Draft for Comments, for the first time, introduces the concept of "cross-border information transfer" in the context of utilizing HGR information.

In our view, if implemented, this mechanism would apply to registrational clinical trial projects under the international cooperative clinical trial filing regime where "neither materials nor information are transferred abroad". This arrangement would help further shorten filing timelines and improve project initiation efficiency. However, neither the current HGR regulations nor the Draft for Comments clearly defines "cross-border transfer of HGR information". In March 2024, the Cyberspace Administration of China ("**CAC**") issued the *Guidelines for Filing Data Export Security Assessment (Second Edition)* and the *Guidelines for Filing Standard Contracts for Cross-Border Transfer of Personal Information (Second Edition)*, which expressly define cross-border data and personal information transfer activities, including transmission abroad of data or personal information collected and generated during domestic operations, or situations where such data or personal information are stored domestically but can be queried, retrieved, downloaded, or exported by overseas entities, as well as other processing activities involving personal information of domestic individuals conducted overseas. With reference to the CAC rules, the concept of "cross-border transfer" may be broader than merely "providing or opening access to," as it may also encompass direct overseas processing of domestic information. Accordingly, the interpretation of "cross-border transfer of HGR information" — including whether factors such as server location, data access permissions, EDC systems, and remote access rights of foreign sponsors or CROs should be considered — remains to be clarified through future implementing rules and regulatory practice.

Narrowed Criteria for Determining Foreign Entities: From "Actual Control" to "50% Equity Interest" Threshold

The Draft for Comments retains the fundamental framework under the Current Implementing Rules restricting activities of foreign entities, namely that foreign entities may not collect or preserve China's HGR within China, or provide China's HGR abroad, and foreign entities utilizing China's HGR for scientific research must cooperate with Chinese entities. Notably, however, compared with the Current Implementing Rules, the Draft for Comments revises the criteria for determining "foreign entities". Article 58 significantly narrows the scope of foreign entities, creating interpretive room for certain joint ventures, enterprises in which foreign investors hold minority equity interests, and contractually controlled entities (VIE-structured entities) to potentially fall outside this scope.

Specifically, the Current Implementing Rules adopt an "actual control" standard for determining foreign entities. In addition to circumstances where foreign entities directly or indirectly hold 50% or more of

equity interests, the Current Implementing Rules also cover situations where foreign entities exert "significant influence" over corporate decision-making or management through veto rights, investment relationships, contractual arrangements, or other mechanisms. By contrast, the Draft for Comments retains only the clear and quantifiable standard of foreign entities "directly or indirectly holding 50% or more of equity interests", without looking through to the influence arising from complex contractual control arrangements or minority shareholdings.

If this proposed amendment is ultimately adopted, compared with the current rules, certain entities — such as companies under Chinese majority shareholding but subject to significant foreign influence through veto rights or other contractual arrangements, including domestic operating entities under VIE structures — may no longer be deemed foreign entities and therefore may be relieved from certain HGR regulatory restrictions. By replacing the broad wording of "being able to control or exert significant influence over an institution's decision-making or management" with a clear equity interest threshold, the Draft for Comments enhances predictability for joint ventures, enterprises in which foreign investors hold minority equity interests, and entities with special structures in assessing HGR compliance. Nevertheless, whether strong veto arrangements, VIE structures, or other contractual arrangements may still be taken into account in determining foreign-entity status on a case-by-case basis remains to be clarified in the final rules, supporting regulations, and future regulatory practice.

Furthermore, it is noteworthy that Article 58 of the Draft for Comments does not appear to contemplate offshore entities controlled by Mainland Chinese entities or individuals (e.g., Cayman Islands vehicles controlled by Chinese shareholders or wholly-owned NewCo subsidiaries established in the U.S. by Chinese domestic enterprises). Consequently, this may result in an inconsistency regarding the scope of "foreign entities" between Article 58 and Article 9 of the Draft for Comments. We understand that such discrepancy will be rectified in the final rules.

Further Increase in Collection Approval Population Thresholds

The *Service Guide for Administrative Licensing Matters on the Collection of Chinese Human Genetic Resources* issued by MOST in 2019 set the population threshold for large-scale population studies requiring collection approval at 500 individuals. The Current Implementing Rules increased the threshold to 3,000 cases, while Article 16 of the Draft for Comments further raises the threshold to 10,000 cases. For large-scale population studies such as cohort studies, cross-sectional studies, clinical studies, and anthropometric studies, this adjustment narrows the scope of collection approval requirements and helps reduce the upfront administrative approval burden for certain medium-sized research projects.

At the same time, with respect to HGR involving important genetic pedigrees and specific regions, the Draft for Comments further implements the catalog mechanism established under the Current Implementing Rules by linking collection approval obligations to officially published catalogs. Only collection of HGR included in such catalogs would require approval, helping companies, medical institutions, and research institutions more clearly determine whether application procedures are necessary. We will continue to closely monitor how such catalogs will be formulated, published, and dynamically updated.

However, while increasing the approval population threshold, the Draft for Comments also prohibits reducing collection quantities or circumventing administrative approval requirements through project splitting or other fragmented arrangements. In our view, future large-scale population studies will still need to adopt reasonable project designs, sample size arrangements, and implementation pathways to avoid being deemed as "circumventing collection approvals" due to project segmentation, thereby triggering compliance risks.

Simplified Procedures for External Provision of Information in Academic Contexts

Under the current HGR regulatory framework, regardless of the usage scenario — including academic exchanges and publication of papers — providing or opening access to HGR information externally generally requires completion of prior reporting procedures and submission of information backups. In practice, such procedures may take one to two weeks to complete. The existing prior reporting obligation is substantively similar to an administrative filing and still applies in academic exchange and publication contexts.

In light of the special circumstances and needs of academic exchanges and publication activities, the Draft for Comments proposes that where HGR information is provided externally or opened for use for the purpose of paper publication or academic conference exchanges, submission of the relevant data to the China National Center for Bioinformation prior to formal publication or the conference shall be deemed completion of the prior reporting obligation, without the need to await approval. This simplification would significantly reduce the compliance burden on relevant parties, including physicians and scholars, when using HGR information in international lectures, exchanges, or publications in international journals, greatly accelerating the process. The "submission equals compliance" approach also more closely aligns with the ordinary meaning of "reporting".

At the same time, it should be noted that under the simplified rules, relevant parties must still ensure that the HGR data submitted in each case are complete in scope and accurate in content, and that such submission is completed before formal publication of the paper or the occurrence of the conference. Accordingly, this remains a form of "prior reporting", unlike certain post-event obligations under other regulatory regimes (such as filing standard contracts for cross-border transfer of personal information).

Emergency Approval and Expedited Approval Mechanisms for Hong Kong and Macau Institutions

With respect to emergency responses to public health incidents and other emergencies, the Draft for Comments is consistent with various regulations and policies issued by regulators in recent years and establishes an emergency approval mechanism for HGR licensing. In the event of a public health emergency, relevant HGR administrative applications may benefit from streamlined application materials and simplified approval procedures, enabling administrative approval to be obtained within as few as five working days.

Meanwhile, in light of the increasingly close cooperation between Mainland China and Hong Kong and Macau in the pharmaceutical and medical device sectors, the Draft for Comments introduces, for the first

time, an expedited approval mechanism for HGR activities involving Hong Kong and Macau institutions. This mechanism allows HGR approval or filing applications involving Hong Kong and Macau institutions to be submitted concurrently with ethics review or clinical trial application procedures, with HGR approval or filing to be granted directly upon the subsequent supplementary submission of ethics approvals, clinical trial approvals, or other required materials. This expedited mechanism may accelerate HGR approval procedures for projects involving Hong Kong and Macau institutions, although relevant parties must still ensure that all required ethics and clinical approvals or supporting documents are obtained.

Notably, the Draft for Comments does not yet clearly define the scope of "HGR activities involving Hong Kong and Macau institutions". First, it remains unclear whether Hong Kong and Macau institutions include Mainland-controlled institutions established in Hong Kong or Macau as referenced in Article 59 of the Draft for Comments, and whether Hong Kong and Macau institutions not Mainland-controlled would still be subject to restrictions applicable to foreign entities. Second, the scope of "HGR activities" may cover the full lifecycle from collection and preservation to utilization and external provision. Finally, whether "involving" Hong Kong and Macau institutions requires such institutions to act as major collaborators or principal recipients of information, or whether a lower level of connection would suffice, remains to be clarified through the final rules, supporting regulations, and future regulatory practice.

Alignment with the Provisions on Administrative Penalty Procedures for Health Authorities: Standardization of the Enforcement Framework

Following the institutional reform under the 2024 amendments to the *Regulations on the Administration of Human Genetic Resources of the People's Republic of China*, which transferred HGR management responsibilities from MOST to the NHC, the Draft for Comments compresses the standalone chapter on administrative penalties under the Current Implementing Rules into a single principle-based provision in Article 57. Rather than enumerating specific enforcement procedures, the Draft for Comments provides that penalty procedures shall directly follow the *Provisions on Administrative Penalty Procedures for Health Authorities*.

This adjustment does not add or remove any categories of unlawful conduct or alter penalty severity at the substantive level (penalties for HGR-related violations remain governed by the *Regulations on the Administration of Human Genetic Resources* and the *Biosecurity Law*), and the core purpose of this adjustment is to enhance consistency within the legal framework. The adjustment indicates that HGR regulation will become more deeply integrated into the existing healthcare supervision system, further strengthening the systematic nature and transparency of enforcement. For enterprises, leveraging the NHC's well-established administrative enforcement mechanisms, regulation will become more systematic and rigorous, with standardized procedures covering the entire process from case filing, investigation and evidence collection, and legal review to hearings, service, and enforcement. Whether such integration will further promote practical enforcement of HGR regulations and whether penalty information will be publicly disclosed remain subject to further regulatory practice.

Conclusion

Overall, while preserving the fundamental framework for safeguarding HGR security in China, the Draft for

Comments is consistent with the stated principle of “strictly regulating what should be regulated while easing restrictions where appropriate”, demonstrating a pragmatic shift in regulatory philosophy from “strict control” to “precision governance”. Measures such as accelerating filing procedures for international cooperative clinical trials, narrowing the criteria for determining foreign entities, raising collection approval population thresholds, simplifying procedures for external provision of information in academic contexts, and introducing expedited approval mechanisms for Hong Kong and Macau institutions are intended to reduce industry compliance burdens and support scientific research and industrial innovation.

Although many key adjustments proposed in the Draft for Comments may still be subject to change before promulgation of the final rules, the Draft for Comments overall sends a clear signal that regulation is moving toward a more precise, pragmatic, and business-friendly direction. We look forward to the final rules achieving an appropriate balance between security and development, and providing the industry with clearer legislative guidance.

3. PRC Rules on Improper Extraterritorial Jurisdiction: Key Takeaways and Implications for Foreign-invested Banks

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Overview

On 7 April 2026, the State Council of the People's Republic of China promulgated the *Regulations of the PRC on Countering Improper Extraterritorial Jurisdiction by Foreign States* (the "**Regulations**"). As the first State Council–level administrative regulation specifically addressing foreign extraterritorial measures targeting Chinese entities and individuals, the issuance of the Regulations marks a significant evolution of China's response to foreign "long-arm jurisdiction". These Regulations are intended to provide greater structural clarity for multinational enterprises navigating conflicts between PRC law and foreign sanctions, export controls, court orders, and other extraterritorial regulatory measures.

To facilitate the understanding of the Regulations, we set out below the key points of the Regulations and their practical implications for foreign-invested banks.

Key Takeaways

I. Scope of Application *(Articles 3, 6 and 8)*

The Regulations apply to the following actors:

1. **Foreign states** that implement improper extraterritorial jurisdiction measures which endanger China's sovereignty, security, development interests, or infringe upon the lawful rights and interests of Chinese citizens or organizations;

2. **Foreign organizations and individuals** that promote, or participate in the implementation of improper extraterritorial jurisdiction measures; and

3. **Organizations and individuals, whether inside or outside China,** that execute or assist in executing improper extraterritorial jurisdiction measures.

II. Types of Countermeasures *(Articles 7 and 8)*

The Regulations establish a dual-track countermeasure framework: (1) Article 7: at the state level – the Chinese authorities may take countermeasures and restrictive measures against relevant countries in respect of diplomacy and foreign affairs, exit and entry, trade, investment, international cooperation, foreign aid and other areas; and (2) Article 8: at the organization/individual level, those foreign organizations/individuals that "promote or participate in the implementation" of improper extraterritorial jurisdiction measures, upon decision by the competent authorities, will be enlisted in the Malicious Entity List, and be subject to a broad range of countermeasures and restrictive measures, including but not limited to, entry bans or deportation, cancellations or restrictions on work or residence permits in China, seizure or freezing of assets within China, prohibitions or restrictions on data transfers from onshore entities to them, or on their conducting commercial transactions with Chinese entities,

prohibitions or restrictions on import and export activities related to China, prohibitions or restrictions on investment within China, prohibition or restriction on the entry of their products, means of transportation and the like, and monetary fines. Importantly, such measures may also be extended to organizations actually controlled by, or established or operated with the participation of, the enlisted entities or individuals.

III. Identification Mechanism *(Articles 6 and 12)*

The Regulations establish a formal identification mechanism for determining whether a foreign law or measure constitutes an improper extraterritorial jurisdiction measure. Under this mechanism, the Ministry of Justice ("**MOJ**"), in coordination with other relevant PRC authorities, is responsible for making such determinations. In conducting the assessment, the authorities may consider, among other factors: (1) whether the measure violates international law and the basic norms governing international relations; (2) whether the conduct subject to the foreign jurisdiction has an appropriate connection to the foreign state concerned; (3) whether the measure endangers China's sovereignty, security, and development interests, or harms the lawful rights and interests of Chinese citizens and organizations; and (4) other factors that should be considered. Once a foreign law or measure is identified and announced by MOJ to be an improper extraterritorial jurisdiction measure, any organization or individual shall not execute or assist in execution of such improper extraterritorial jurisdiction measure. Competent PRC authorities will be entitled to take measures such as on-site inspections, and consulting and copying relevant materials against organizations or individuals suspected of executing or assisting in executing improper extraterritorial jurisdiction measures under Article 12 of the Regulations.

IV. Prohibition Execution Order *(Articles 13 and 17)*

On the basis of the general prohibition that any organization or individual shall not execute or assist in execution of an improper extraterritorial jurisdiction measure as announced by MOJ under Article 6 of the Regulations, Article 13 further authorizes the MOJ to issue a Prohibition Execution Order, i.e., an order prohibiting the execution of improper extraterritorial jurisdiction measures by organizations or individuals that execute or assist in executing such measures. The violation of the aforementioned general prohibition will invite regulatory talks or order to correction by competent PRC authorities, and, upon decision by the MOJ, a Prohibition Execution Order. The violation of a Prohibition Execution Order will result in more severe penalties under Article 17, including but not limited to: restrictions or prohibitions on participation in government procurement and bidding; restrictions or prohibitions on the import and export, international trade in services, and other activities in relation to relevant goods and technologies; restrictions or prohibitions on cross-border data transfers; restrictions or prohibitions on entry into, exit from, or residence in China; and monetary fines.

V. Exemption Applications *(Articles 6, 9 and 11)*

The Regulations provide for multiple exemption mechanisms to address situations where strict compliance with the prohibitions may give rise to undue hardship or unavoidable legal conflicts.

1. **Exemption for executing improper extraterritorial jurisdiction measures (Article 6):** Where

PRC citizens or organizations, due to special circumstances, are genuinely required to execute an improper extraterritorial jurisdiction measure, they may apply to the MOJ for an exemption. We understand such applications should be supported by a detailed compliance impact assessment, addressing the implications of compliance or non-compliance on business operations, as well as the scope of measures that need to be executed or assisted in execution. Upon approval, the applicant may, within a specified scope and under prescribed conditions, be permitted to execute or assist in executing the relevant improper extraterritorial jurisdiction measure.

2. **Application for relief by parties subject to countermeasures or restrictive measures (Article 9):** Organizations or individuals subject to countermeasures or restrictive measures may apply for the suspension, modification, or revocation of such measures. The applicant is required to provide facts and justifications, including evidence of rectification of the relevant conduct.

3. **Exemption for transactions with parties subject to countermeasures or restrictive measures (Article 11):** Where an organization or individual has a genuine need, under special circumstances, to engage in otherwise prohibited or restricted activities with an entity or individual subject to countermeasures or restrictive measures, it may apply to the authority that imposed the relevant measures for approval. Upon approval, such transactions may be carried out.

VI. Remedies *(Article 14)*

Chinese citizens or organizations harmed by improper extraterritorial jurisdiction measures may file civil suits against the organizations or individuals that executed such measures and may seek cessation of the infringing conduct as well as compensation for losses in Chinese courts.

VII. Interaction with Other PRC Laws *(Article 19)*

Article 19 clarifies that where matters involving improper extraterritorial jurisdiction intersect with areas such as anti-corruption, anti-monopoly, unfair competition, export controls, data security, or judicial assistance, specific laws and regulations governing those areas shall prevail.

In addition, Article 19(2) of the Regulations provides that where a foreign country, in violation of international law and the basic norms of international relations, improperly prohibits or restricts Chinese citizens and organizations from engaging in normal economic, trade, and related activities with third countries (regions) and their citizens and organizations, such matters shall be handled in accordance with other relevant state provisions where applicable. Accordingly, the *Rules on Blocking Improper Extraterritorial Application of Foreign Laws and Measures* ("**Blocking Rules**") shall still take priority in addressing the blocking of improper extraterritorial application in the economic and trade area. It is worth noting that on May 2, 2026, the Ministry of Commerce, for the first time, issued a blocking order pursuant to the Blocking Rules, providing a reference for the subsequent application of the Regulations.

Practical Considerations for Foreign-Invested Banks

In light of the Regulations, foreign-invested banks operating in China, including PRC subsidiaries and branches of foreign banks, should consider the following actions:

I. Enhanced Due Diligence and Counterparty Screening

Foreign-invested banks shall integrate the new Chinese regulatory lists, namely the improper extraterritorial jurisdiction measures announcements, the Malicious Entity List and any Prohibition Execution Orders issued by the MOJ, into their automated screening systems, to ensure the banks will not execute or assist in the execution of the announced improper measures, not transact with any organization/individual on the Malicious Entity List or otherwise has any connection with such enlisted organization/individual, and not violate the Prohibition Execution Orders.

II. Contractual Modifications to Mitigate Compliance Conflicts

Foreign-invested banks may amend their standard contractual templates, including but not limited to, account opening forms, loan agreements, trade finance documents, derivatives documents, to address the conflict between foreign legal demands and Chinese blocking obligations. The most critical clause to include is a compliance conflict clause, which provides that the performance of any provisions relating to account closure, transaction restrictions, account or asset freezes, termination of agreements, and other related measures based on foreign sanctions shall be subject to compliance with PRC laws and regulations and the requirements of competent authorities. In addition, the contractual documentation should incorporate an exemption clause for compliance with the Regulations - where a bank's performance of contractual obligations would result in a violation of the Regulations (e.g., the counterparty is enlisted in the Malicious Entity List and the bank is prohibited from dealing with such counterparty), such non-performance shall not constitute a default. This clause should explicitly reference Chinese blocking laws (or specifically the Regulations) as a force majeure event or a legal prohibition that excuses performance.

The banks should also consider the allocation of regulatory and compliance risk when the counterparty invokes the improper extraterritorial measures as a force majeure or change in law event to try to exempt itself from performing the obligations, the banks may consider excluding the MOJ identified improper extraterritorial measures as the basis for invoking force majeure or change in law event.

III. Proactive Use of the Exemption Mechanism

The exemption pathway under the Regulations is the bank's primary tool for navigating direct legal conflicts between Chinese law and foreign long-arm measures. Whenever the bank faces a situation where compliance with a foreign demand is also prohibited under the Regulations, it should document the conflict and internally assess whether to apply to the MOJ for an exemption to avoid significant harm.

IV. Monitoring the Application and Enforcement Trends of the Regulations

Banks should continuously monitor the subsequent developments and enforcement approaches of the MOJ and other related authorities in applying the Regulations, including whether further rules or guidance will be issued in relation to the Regulations, as well as practical examples of how the Regulations interact and coordinate with other Chinese laws.

4. China New Biomedical Technology Regulations (Order No. 818) Enter into Force – Dual-Track System for Product Registration / Clinical Translation and Application Finally Takes Effect

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Legislative Background of Order No. 818

In recent years, with the rapid development of cutting-edge biomedical technologies such as cell therapy, assisted reproductive technology, and brain-computer interfaces technology, a large number of enterprises have invested in R&D activities in related fields. Regulatory authorities have also been continuously exploring a dual-track regulatory framework for "drugs/medical devices" and "technologies". On November 29, 2024, the Standing Committee of the Seventh People's Congress of Hainan Province reviewed and adopted the *Regulations on the Promotion of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port*. On January 24, 2025, the Health Commission of Hainan Province issued the *Implementation Measures for the Translation and Application of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port (Provisional)* (the aforementioned documents are collectively referred to as the "**Hainan Boao Regulations**"), under which a pilot program was launched in the pilot zone for the clinical study, translation and application of new biomedical technologies[4]. On October 10, 2025, the State Council of the People's Republic of China officially issued the *Regulations on the Administration of Clinical Study and Clinical Translation and Application of New Biomedical Technologies* ("**Order No. 818**"), establishing a regulatory framework for clinical study and clinical translation and application of new biomedical technologies ("**New Biomedical Technologies**") at the level of administrative regulations, which officially came into force on May 1, 2026 (For a detailed analysis of *Order No. 818*, please refer to: *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*).

Following the issuance of *Order No. 818*, the industry responded enthusiastically. Local authorities have also issued relevant documents aimed at implementing *Order No. 818*. For example, the Guangdong Quality Control Center for Stem/Somatic Cell Clinical Study, established by the Guangdong Health Commission, issued the *Guidelines for the Filing of Clinical Studies on New Biomedical Technologies (Stem/Somatic Cell) in Guangdong Province (Trial)* on February 11, 2026, to implement the filing of stem/somatic cell clinical study under *Order No. 818* in Guangdong. We have also received inquiries from domestic and foreign enterprises regarding *Order No. 818*, such as the application scope of *Order No. 818*, the harmonization between the New Biomedical Technologies translation and application pathway and the drug/medical device registration pathway, whether foreign-invested enterprises may serve as

[3] Yixi Zhao has contributions to this article.

[4] As of April 9, 2026, the pilot zone has approved 29 cutting-edge new biomedical technology projects, covering various refractory diseases including tumors, lung function impairment, neurodegenerative diseases, blood disorders, liver function impairment, and joint degenerative lesions. See *Hainan Daily*, "*29 Cutting-Edge New Biomedical Technology Projects Land in Boao Lecheng*", April 9, 2026, https://www.zmgrc.gov.cn/show-32177.html.

clinical study initiators, and the requirements for medical institutions translating and applying New Biomedical Technologies.

Prior to the effective date of *Order No. 818*, the National Health Commission (the "**NHC**") released the *Work Standards for the Approval of Clinical Translation and Application of New Biomedical Technologies (Draft for Comments)* (the "**Work Standards (Draft for Comments)**") on April 19, while on April 30, the NHC released *Work Standards for the Approval of Clinical Translation and Application of New Biomedical Technologies (Trial)* (the "**Work Standards (Trial)**") , the *Guiding Principles for the Classification of New Biomedical Technologies and Drugs/Medical Devices (Provisional)* (the "**Classification Guiding Principles**"), and the *Filing Guidance List for Clinical Study on New Biomedical Technologies* (the "**Filing Guidance List**"), and the China National Center for Biotechnology Development (the "**CNCBD**") issued the *Guidelines for Filing of Clinical Studies* on Fourteen New Biomedical Technologies (Version 1), which set forth institutional and personnel requirements, preparation and quality control of investigational products, and other technical requirements for new technologies such as brain-computer interfaces, xenotransplantation, and somatic cell/stem cell technologies (collectively, the "**Detailed Rules**"). The Detailed Rules provide guidance for industry in identifying New Biomedical Technologies, clarifying the relationship between the regulatory pathways for New Biomedical Technologies and those for drugs and medical devices, and implementing subsequent clinical translation and application.

Drawing on the perspectives of various stakeholders in practice, and building upon existing analyses of *Order No. 818*, this article further analyzes several key points reflected in the *Detailed Rules*, aims to provide reference for enterprises in assessing future product/technology pathways, conducting clinical study and clinical translation and application of New Biomedical Technologies.

Key Analysis of the Detailed Rules

I. Scope of New Biomedical Technologies

Pursuant to the *Classification Guiding Principles*, New Biomedical Technologies primarily encompass (i) new biomedical technologies that are difficult to develop into medical devices, and (ii) new biomedical technologies that are highly innovative, highly personalized, and have not yet been – or are difficult to – developed into drugs. From a practical standpoint, defining the specific scope of New Biomedical Technologies is particularly important.

Regarding the scope of New Biomedical Technologies, compared with the *Hainan Boao Regulations* established during the pilot period, which enumerated several New Biomedical Technologies such as "cell therapy, gene therapy, tissue engineering, etc.", *Order No. 818* defines the connotation of New Biomedical Technologies. Article 3 of *Order No. 818* defines "New Biomedical Technologies" as medical techniques and measures that are intended to assess health status, prevent or treat diseases, or promote health, which apply biological principles, act at the cellular or molecular level of the human body, and have not yet been clinically applied within China.

Building on *Order No. 818*, the NHC has established the *Filing Guidance List* to clearly define the scope of New Biomedical Technologies at early stages, including preclinical study and clinical study. Pursuant to the *Classification Guiding Principles*, this list is subject to inclusion and removal

mechanisms. Accordingly, if a New Biomedical Technology with a similar mechanism has already completed clinical translation and application, there will be uncertainty as to whether subsequent New Biomedical Technologies can proceed with translation, pending the NHC and the National Medical Products Administration (the "**NMPA**")'s organization of an expert review on whether such technologies should be removed from the *Filing Guidance List*.

Accordingly, we understand that *Order No. 818* imposes stringent requirements on the innovativeness of New Biomedical Technologies. New Biomedical Technologies at the same stage (e.g., clinical study stage) with the substantially same mechanisms and indications should closely monitor the translational progress of other similar technologies. Those applying for translation at a later stage may be removed from the *Filing Guidance List* due to the prior successful clinical translation of similar technologies, thereby losing the opportunity to achieve application through the New Biomedical Technology pathway.

Additionally, we note that the final version of the *Filing Guidance List* removed "new technologies for immune cell therapy" compared to the draft for comment released in March 2026. In this regard, we understand that such new technologies fall within the scope of "new technologies for somatic cell therapy" under the *Filing Guidance List*. Biologically, "somatic cells" is a broader concept that encompasses stem cells, immune cells, tissue cells, and other cell types. However, in defining new technologies for somatic cell therapy, the final version narrows the scope to "mature/functionally differentiated cells", thereby excluding stem cells – as undifferentiated cells – from this subcategory (which are addressed under separate subcategories), while immune cells, being mature/functionally differentiated cells, are fully covered by this subcategory.

II. The impact of the Classification Guiding Principles on the IIT Regulation

The *Classification Guiding Principles* clarifies that if a drug or medical device with substantially the same indication and mechanism has been approved for marketing in China, or if a biomedical technology has already been approved for clinical translation and application, the NHC shall, in consultation with NMPA, promptly organize an expert review and make adjustments based on the review outcome. If a technology is removed from the list following such review, any new related clinical study initiated by an investigator thereafter shall be conducted in compliance with the relevant provisions of the *Measures for the Administration of Investigator-Initiated Clinical Study Conducted by Medical and Health Institutions (2024)* (the "**IIT Regulation**").

However, Article 12 of the *IIT Regulation* provides that clinical study using surgical procedures, operations, physical therapy, psychotherapy, behavioral interventions, clinical treatment protocols, population-based health measures, or biomedical technologies as interventions shall use drugs, medical devices, or other products that have already been approved for marketing. We understand that the *IIT Regulation* may be amended in due course to add, alongside drugs and medical devices already approved for marketing, New Biomedical Technologies that have already been approved for clinical translation and application. This would also address the practical need to ensure that, if a New Biomedical Technology has been removed from the *Filing Guidance List* following review and approved for clinical translation and application as a medical technology, it may subsequently

participate in general IITs in compliance with the requirements of the *IIT Regulation*.

III. Who Determines Whether a Technology Intended for Clinical Study Qualifies as a New Biomedical Technology?

Pursuant to Article 2 of the *Classification Guiding Principles*, clinical study initiators shall, with reference to the *Filing Guidance List*, independently determine the classification of the technology intended for New Biomedical Technology clinical study. Meanwhile, the NHC entrusts a professional institution to provide consultation and guidance services related to such classification. At present, such a professional institution has yet to be identified, and this matter remains to be further observed in practice.

However, Article 14 of *Order No. 818* stipulates that clinical study may only proceed after passing both academic and ethics reviews by the clinical sites. Therefore, in practice, clinical sites (such as hospitals) have significant discretion in deciding whether to allow clinical study initiators to pursue clinical study under the New Biomedical Technology pathway. Accordingly, companies should engage proactively with hospitals to reach consensus on classification and the applicable regulatory pathway, so as to facilitate the advancement of clinical studies.

For technologies determined not to fall within New Biomedical Technologies, if commercialization is intended, clinical trials for registration purposes should be conducted in accordance with the *Good Clinical Practice for Drugs* and the *Good Clinical Practice for Medical Devices*, and be subject to the corresponding regulatory oversight.

IV. Scope, Conditions, Procedures, and Outstanding Issues for the Clinical Translation and Application of New Biomedical Technologies

Articles 3 and 6 of the *Work Standards (Trial)* provide detailed clarification on the scope of New Biomedical Technologies eligible for clinical translation and application. First, such technologies must be included in the *Filing Guidance List*, and must have completed clinical study. The technologies must have been proven safe and effective through such study, compliant with ethical principles. In addition, during the clinical study stage, the technology must have been independently implemented by multiple centers in accordance with clinical application operation standards, with consistent conclusions reached on safety and efficacy. Second, the technology must meet one of the following conditions:

1. It is highly personalized, and no drug based on the similar mechanism has obtained marketing authorization or initiated confirmatory clinical trials in China; or

2. It is intended for the treatment of rare diseases and no drug with the similar mechanism and indication has obtained marketing authorization or initiated confirmatory clinical trials in China.

The *Work Standards (Trial)* does not provide explicit definitions for “highly personalized” or “similar mechanism”. However, in the official interpretation of the *Work Standards (Trial)* released concurrently by the NHC, it is stated that the criteria for determining “similar mechanism” will vary depending on the characteristics of different technologies, and separate rules will be developed.

Furthermore, the *Work Standards (Trial)* does not extend the requirement of "no similar mechanism" to foreign jurisdictions, but merely requires that no drug with the similar mechanism has obtained marketing authorization or initiated confirmatory clinical trials in China. This means that even if a foreign drug with the similar mechanism has been approved for marketing or entered confirmatory clinical trials abroad, a domestic enterprise may still apply for clinical translation and application of such technology in China (for example, by introducing foreign technology through a license-in arrangement and achieving clinical translation and application of the New Biomedical Technology domestically).

Additionally, the requirements regarding "obtaining marketing authorization" and "initiating confirmatory clinical trials" are relatively clear. We understand that, since the aforementioned conditions require that there are no drugs with similar mechanism already marketed or in confirmatory clinical trials in China, technologies similar to drugs already on the market will lack the possibility of applying for clinical translation and application. Examples include cell and gene therapy ("**CGT**") technologies similar to marketed CGT products, or to CGT drugs that have already initiated confirmatory clinical trials (such as Phase III clinical trials). On the other hand, if multiple technologies or drugs with similar mechanisms and the same indications are all still in the IIT stage, similar New Biomedical Technologies would still retain the possibility of applying for clinical translation and application.

Notably, for New Biomedical Technologies eligible for translation and application in the treatment of rare diseases, the *Working Standards (Draft for Comments)* explicitly required that such rare diseases be included in the Rare Disease Directory published by the NHC. However, the reference to the "Rare Disease Directory" was removed in the *Working Standards (Trial)*. We understand that this may signal greater flexibility in the clinical translation and application of New Biomedical Technologies for rare disease treatment, though it cannot be ruled out that regulators may in the future continue to manage such technologies through a directory-based approach.

Overall, we understand that *Order No. 818* and its *Detailed Rules* clarify the boundaries for clinical translation and application through New Biomedical Technologies. For technologies that are truly innovative and highly personalized but have not yet been – or are difficult to – developed into drugs or medical devices (such as brain-computer interface technology), a pathway is provided for clinical translation and application. Conversely, for drugs and medical devices that already possess a clear product profile and are capable of standardized, large-scale production, the route of registration as drugs and medical devices should continue to apply. For example, regarding in vivo CAR-T technology – a topic of significant industry interest – it may be possible to conduct clinical trials as a New Biomedical Technology. However, whether clinical translation and application will be permitted in the future will depend on the regulatory stance at that time and the development of the technology itself. If standardized, large-scale production of in vivo CAR-T products emerges, such products may fail to satisfy the high degree of personalization requirement and thus be ineligible for clinical translation and application.

V. Are Fees Permissible for the Clinical Translation and Application of New Biomedical Technologies?

According to Article 34 of *Order No. 818*, medical institutions may charge fees for the authorized clinical translation and application of New Biomedical Technologies in accordance with relevant regulations. This implies that such technologies can now enter a commercial revenue-generating stage. This has been a primary focus of industry attention, as it provides a commercialization pathway through clinical translation and application under *Order No. 818*, alongside the traditional market authorization channels for drugs and medical devices.

We note that the *Application Form for Clinical Translation and Application of New Biomedical Technologies*, which is an appendix to the *Work Standards (Trial)*, stipulates that the applicant shall submit a cost statement for the clinical application of the technology. At present, the *Work Standards (Trial)* does not clarify the price management procedures following the clinical application, such as whether a price filing is required. This remains an area to be observed in future practice.

However, it is important to note that Article 20 of *Order No. 818* remains explicit that no fees may be charged to participants during the clinical study stage of New Biomedical Technologies. Regulators have not relaxed their stance on this patient-centric principle. The prohibition against charging fees for clinical studies continues to be a non-negotiable "red line".

VI. Whether Enterprises May Freely Choose Between Technology Translation and Product Registration Pathways, and The Submission and Use of Clinical Data

Pursuant to Article 55 of *Order No. 818*, we understand that clinical trials conducted for the purpose of product registration remain subject to the *Drug Administration Law* and the *Regulations on the Supervision and Administration of Medical Devices*, rather than *Order No. 818*. However, we have observed the parallel operation of these two pathways in practice. For instance, data generated from clinical study and translation and application of New Biomedical Technologies within the pilot zone can still be referenced as real-world data during the drug marketing authorization process[5].

We understand that clinical study on New Biomedical Technologies is subject to different regulatory rules from drug clinical trials conducted for registration purposes. Clinical data generated in New Biomedical Technology clinical study, unlike clinical data from IND trials, may not be directly used to apply for drug marketing authorization. However, companies still have the opportunity to engage in close communication with regulators prior to applying for marketing authorization of drugs and may have the chance to submit clinical data generated from New Biomedical Technology clinical study as real-world data for regulatory reference. It is worth noting that, unlike drugs, most clinical trials for medical devices conducted for registration purposes do not require an IND approval (except for those

[5] The *Interpretation of the Regulations on the Promotion of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port*: Strengthen the application of real-world data; support medical institutions in the pilot zone in the effective accumulation of real-world data during the process of translation and application of New Biomedical Technologies; enhance the applicability of real-world data; and provide data references for products already marketed overseas when applying for marketing authorization in China. Please refer to: https://v4.hainanpc.gov.cn/eportal/ui?pageId=000127408b2d40c8ba893bd463d02c9c&articleKey=c2b5c3af547b4b5eaf0175d184cd0ca5&columnId=7760d1655bc4469391f12e9b269c788c.

falling within the catalog of Class III medical devices subject to clinical trial examination and approval). Therefore, if a technology developed through New Biomedical Technology clinical study is classified as a medical device at the clinical translation and application stage, such clinical study data will have a greater chance of being accepted by the regulatory authorities when applying for marketing registration. We will continue to monitor how this unfolds in practice.

Additionally, as to whether enterprises may freely choose between the two pathways of product registration and clinical translation and application, we understand under the *Classification Guiding Principles* that during the clinical study stage, an enterprise may independently assess based on the *Filing Guidance List* whether the technology falls within the scope of New Biomedical Technologies or constitutes a drug or medical device. At the subsequent translation stage, however, Article 3 of the *Working Standards (Trial)* stipulates that technologies meeting the definition of a medical device do not fall within the scope of examination and approval for clinical translation and application, and shall instead undergo relevant registration procedures pursuant to medical device regulations. This indicates that medical devices cannot be translated as New Biomedical Technologies. Nevertheless, with respect to drugs and drug-led combination products, the *Working Standards (Trial)* does not preclude enterprises from choosing either the technology translation pathway or the product registration pathway. Of course, from an efficiency perspective, if a technology can be directly translated as a New Biomedical Technology, a lot of enterprises would prefer to avoid registering it as a drug, thereby eliminating the need to file a new IND and NDA.

VII. Implications of Order No. 818 for IITs on Stem Cells and Somatic Cells

We understand that with the official entry into force of *Order No. 818*, the regulatory environment for IITs involving stem and somatic cell therapies is expected to tighten. Historically, cell therapy companies operated within a distinct regulatory lane. When conducting IITs, they typically followed specialized measures and guidelines, such as the *Administrative Measures on Stem Cell Clinical Study (Trial)* and the *Work Guidelines for Somatic Cell Clinical Study (Trial)*. This specific pathway sets them apart from other IITs governed by the general *IIT Regulation*.

Since *Order No. 818* came into effect on May 1, it is our understanding that stem cell and somatic cell therapies will be categorized as New Biomedical Technologies. Although *Order No. 818* has not yet explicitly superseded the aforementioned specific regulations, we believe it may materially reshape the regulatory landscape for IITs on cell therapy. For instance, regulatory authorities may subsequently require all cell therapy IITs to be filed strictly via the New Biomedical Technology pathway, thereby precluding relevant enterprises from invoking the previous specialized regulations to conduct IIT studies. The precise regulatory stance remains to be further clarified by forthcoming implementing rules and administrative practices.

VIII. Hospitals Implementing Approved Translation and Applications for New Biomedical Technologies

During the pilot phase, the *Hainan Boao Regulations* established various specific conditions for

hospitals implementing approved translation and application for New Biomedical Technologies [6]. Although Article 11 of *Order No. 818* sets forth the requirements for institutions conducting clinical studies of New Biomedical Technologies (such as Grade 3A hospital status), it does not explicitly define the qualifications for hospitals to translate and apply such technologies in clinical practice. However, Article 33 of *Order No. 818* mentions that when the NHC approves the clinical translation and application of a New Biomedical Technology, it shall publish the name of the technology, the qualifications required for the medical institutions and health professionals utilizing said technology, and the operational specifications for its clinical application.

On May 1, 2026, the CNCBD issued the *Guidelines for Risk Classification of New Biomedical Technologies*, which, taking into consideration dimensions such as the complexity of technical operations, reversibility of effects on the human body, and impacts on public health and social ethics, classifies the four major categories of New Biomedical Technologies (excluding brain-computer interface technology) in the *Filing Guidance List* into three risk levels: high-risk, medium-risk, and low-risk. According to the *Work Standards (Trial)*, high-risk technologies may only be clinically applied within medical institutions that participated in the clinical study and meet the conditions for five years following approval; medium-risk technologies for three years following approval; and low-risk technologies for one year following approval. Upon expiration of such periods, if no change has occurred in the understanding of their safety and efficacy, no serious adverse reactions or uncontrollable risks have emerged, no major social stability risks have been caused or major events affecting social stability have occurred, or if re-evaluation confirms that benefits far outweigh risks, other qualified medical institutions may then conduct clinical application. Furthermore, the *Work Standards (Trial)* explicitly requires that other qualified medical institutions, when conducting clinical application of the aforementioned New Biomedical Technologies, shall perform filing procedures with reference to Restricted Medical Technologies as in the *Administrative Measures for the Clinical Application of Medical Technologies*. We understand that, when carrying out clinical application of such technologies, other medical institutions shall also fulfill filing procedures with the health administrative department that issued their Medical Institution Practicing License, pursuant to the *Administrative Measures for the Clinical Application of Medical Technologies*.

We understand that the regulators have been considering the issue of applying such New Biomedical Technologies at institutions other than the original clinical sites. Article 6 of the *Work Standards (Trial)*, which sets out the conditions of clinical translation and application of New Biomedical Technologies, includes the technology must have been independently implemented by multiple centers during the clinical study stage, in accordance with clinical application operation standards, with consistent conclusions reached on safety and efficacy. This suggests that New Biomedical Technologies intended for clinical translation and application shall meet the standard of being reproducible across different institutions. However, before such technologies are applied at other institutions, different

[6] The *Hainan Boao Regulations* stipulate specific requirements for hospitals utilizing approved translational technologies. These include: maintaining Grade 3A hospital status; maintaining both academic and ethics committees; possessing appropriate personnel, equipment, and facilities; establishing quality management systems and risk control frameworks for the translation and application of new technologies; and formulating emergency contingency plans for handling adverse events and medical incidents.

periods should be set based on different risk levels to collect adverse reaction data and monitor safety and efficacy. We understand that this is a "safety observation period" established by the regulatory authorities for such new technologies, reflecting a balance between patient accessibility and technological safety.

IX. Coordination with Human Genetic Resources Regulation

The appendix to the *Work Standards (Trial)* expressly provides that a filing or approval document for human genetic resources should be submitted when applying for translation and application of New Biomedical Technologies. The *Guidelines for the Filing of Clinical Studies on New Biomedical Technologies (Stem/Somatic Cell) in Guangdong Province (Trial)* also state that a filing or approval document for human genetic resources is required for clinical study filing, and such filing or approval document falls under "other materials prescribed by the health department under the State Council" as set forth in Article 16 (9) of *Order No. 818*. However, whether the practices and positions that have developed in the filing or approval practice for human genetic resources will apply to the filing of clinical studies on New Biomedical Technologies remains to be seen.

Given that clinical study on New Biomedical Technologies under the *Order No. 818* is not conducted for the purpose of product registration, the relevant clinical study agreements entered into between enterprises and hospitals may in the future be subject to provisions under China's human genetic resource administration stipulating that patent rights to resulting outcomes shall be jointly owned by both parties. Accordingly, enterprises intending to conduct clinical studies involving New Biomedical Technologies should carefully consider the relevant patent-sharing requirements and make advance plans regarding patent ownership.

X. Competent Authorities and Procedures for Approval of Clinical Translation and Application of New Biomedical Technologies

During the pilot phase, the *Hainan Boao Regulations* set out detailed procedures for the clinical translation and application of New Biomedical Technologies[7]. *Order No. 818* only briefly addresses the process for translation and application of New Biomedical Technologies, simply providing that translation requires review and approval by the NHC. The *Work Standards (Trial)*, however, clarifies the approval authorities and procedures for the clinical translation and application of New Biomedical Technologies.

First, the approval process will involve multiple authorities and institutions, including the NHC, local health commissions, CNCBD, and the National Center for Medical Service Administration of the NHC

[7] The *Hainan Boao Regulations* set out relatively detailed procedures for the clinical translation and application of New Biomedical Technologies. For example, clinical studies must demonstrate that the New Biomedical Technology is safe, effective, and compliant with ethics principles, and the hospital applies to the medical products administration for translation and application. However, the hospital itself must first complete an access qualification assessment to ensure that it meets qualification requirements such as being a Grade 3A hospital and having a quality and risk control system. Once the application is accepted by the pilot zone's medical products administration, it should be transferred to the pilot zone's management agency for a technical evaluation, and the pilot zone's medical products administration shall then make the decision on whether to approve the translation and application based on the evaluation results. Finally, once approved, the New Biomedical Technologies shall be submitted to the local healthcare security administration and the local health commission for price filing.

(the "**NCMSA**"). The NHC holds the ultimate approval authority to determine whether a new technology may be translated and applied. However, the specific review work, including materials verification and technical and ethics evaluations, will be delegated to the CNCBD, and the NHC will make its decision based on the evaluation opinion of the CNCBD. The CNCBD is also the department responsible for the regulation of human genetic resources. The NCMSA is responsible for coordinating with the CNCBD to conduct re-evaluation of technologies already approved for clinical translation and application. If the understanding of the safety or efficacy of an approved technology changes, or serious adverse reactions, uncontrollable risks, or major risks to social stability arise during application, the NCMSA will organize a re-evaluation of its safety and efficacy. Application of the technology will be suspended during the re-evaluation period. If the re-evaluation determines that safety and efficacy cannot be ensured, the NHC will prohibit application of the technology and make a public announcement.

Additionally, for technologies used to treat diseases that are seriously life-threatening and for which no effective treatment is available, or technologies urgently needed for public health, the applicant may submit a priority review and approval application form when filing the application for clinical translation and application.

Under public health emergency circumstances, New Biomedical Technologies still in the clinical study stage may be applied on an exceptional basis. To address particularly serious public health emergencies or other emergencies that pose a serious threat to public health, if the NHC, after organizing an expert review, determines it to be necessary, it may approve the emergency application of new technologies currently undergoing clinical study within a certain scope and time limit; specific implementing rules shall be formulated separately.

Conclusion

We understand that the clinical translation and application of New Biomedical Technologies opens up another pathway in addition to the marketing authorization of drugs and medical devices, which is of landmark significance in the history of drug and medical device regulation in China. However, this pathway differs from the drug and medical device registration regulatory pathway in terms of its purpose and requirements, and companies may make decisions based on their own business considerations and the development status of their technologies.

On the one hand, the drug/medical device registration pathway is relatively mature, stable, and highly predictable. Once a product is approved for marketing, it may be sold and used nationwide, without being limited to specific medical institutions, and may have the opportunity to be included in the *National Reimbursement Drug List*, thereby forming a stable payment mechanism. However, this pathway generally requires the completion of systematic clinical trials, involves a longer timeline and greater capital investment, and requires the marketing authorization holders("**MAH**") to continuously fulfill comprehensive responsibilities, including GxP compliance. On the other hand, the regulatory system for the technology translation and application pathway is being rapidly improved. For cutting-edge innovative technologies, this pathway may enable faster translation by leveraging the policy window and may bring certain policy benefits. However, the relevant regulatory requirements are also stringent and should not be

underestimated. The scope of medical institutions to which this pathway applies is relatively limited, which is also related to the complexity of New Biomedical Technologies themselves. In addition, arrangements regarding intellectual property ownership and allocation of benefits in collaboration with medical institutions should also be carefully designed. We look forward to the promulgation and implementation of more regulatory rules on New Biomedical Technologies in the future, so as to set a steady course for the new regulatory framework and stimulate its vitality, thereby enabling it to complement the established and continuously improving drug and medical device marketing authorization system, and jointly creating greater benefits for patients worldwide.

5. Domestic Remedies for Overseas Securities Fraud: Insights from the Extraterritorial Application of the PRC Securities Law

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In 2026, the Beijing Financial Court and the High People's Court of Beijing Municipality（"**Beijing High People's Court**"）ruled that Chinese mainland courts had jurisdiction over securities fraud involving a Cayman Islands company listed on the Hong Kong Stock Exchange (HKEX). This landmark decision sets a precedent as the first instance in which judicial authorities in Chinese mainland applied the Securities Law of the PRC (the "**Securities Law**") extraterritorially. The decision is recognized as a "typical case" and has been included in the *Report on the Work of the Supreme People's Court (2026)*[8]. Its importance is exemplified by an April 20, 2026, media interview in which Judge Ding Yuxiang, Chief Judge of the Second Civil Division of the Beijing Financial Court, reaffirmed the court's view that "Article 2, Paragraph 4 of the Securities Law can be invoked whenever the lawful rights and interests of domestic investors are damaged"[9].

From a practical perspective, this ruling strengthens protections for mainland Chinese investors and potentially offers a more convenient means of seeking recovery in instances of overseas securities fraud. In this article, we analyze the feasibility and practical advantages of domestic investors in instituting actions in mainland Chinese courts with respect to overseas securities fraud under the extraterritorial provisions of the Securities Law.

Application of long-arm jurisdiction under the Securities Law

Article 2, paragraph 4 of the Securities Law contains a long-arm jurisdiction provision stating: "Where the issuance and transaction of securities outside the territory of the People's Republic China have disrupted the market order within the territory of the People's Republic of China and damaged the legitimate rights and interests of investors within the territory, such activities shall be handled and investigated for legal responsibility in accordance with the relevant provisions of this Law". Previously, there was a lack of clear and consistent views within China's legislative, judicial, and academic circles regarding the application scenarios and conditions of this provision. In particular, there lacked authoritative judicial precedent regarding whether exercise of the provision required both market disruption and damage to investor rights and interests or whether it was sufficient to satisfy only one of these two conditions.

In the case, the Beijing Financial Court and the Beijing High People's Court explicitly ruled that it was necessary only to satisfy one of the two conditions to exercise long-arm jurisdiction provision. This established a judicial view that each condition serves as an alternative to the other. The case has been

[8] See Beijing Financial Court: "Landmark Case | First Ruling Establishing Jurisdiction over Securities Fraud Lawsuits Involving Hong Kong-Listed Foreign Companies That Meet Statutory Requirements", https://mp.weixin.qq.com/s/75H3Axbc0TVhesGnLcvh2w; Beijing Financial Court: "Focus on: A Look at the Beijing Financial Court in the Work Report of the Supreme People's Court", https://mp.weixin.qq.com/s/ajX3uiRCdFN1dn37cJoLjw?scene=1&click_id=48.

[9] See Legal Daily: "Beijing Financial Court Explains the 'First Case of Extraterritorial Application of the Securities Law': Jurisdiction Applies Whenever the Lawful Rights and Interests of Domestic Investors Are Damaged", https://mp.weixin.qq.com/s/j3OnZKYxzDQNBIxh1NjISg.

included in the *Report on the Work of the Supreme People's Court (2026)*, which to a significant extent reflects a top-down consensus within the judicial authorities on this issue. Therefore, we expect that Chinese courts may exercise long-arm jurisdiction under the Securities Law in relation to cases that concern damages to the rights and interests of investors, even if they do not rise to the level of disrupting the market order in China.

The effect of long-arm jurisdiction under the Securities Law

I. What substantive rules apply to foreign-related securities fraud litigation initiated in China?

Article 2, Paragraph 4 of the Securities Law explicitly provides that "such activities shall be handled and investigated for legal responsibility in accordance with the relevant provisions of this Law". The fundamental requirement and original legislative intent of this provision is to permit Chinese courts to adjudicate disputes arising from overseas securities offerings by applying the Securities Law and relevant judicial rules, including *Several Provisions of the Supreme People's Court on Trying Cases of Civil Compensation Arising from False Statements in Securities Market* ("**False Statement Provisions**") and the *Minutes of the National Courts Symposium on the Trial of Bond Disputes*. Long-arm jurisdiction under the Securities Law is not necessarily abrogated by offering documents or transaction agreements that stipulate the application of foreign law because long-arm jurisdiction under this provision involves judicial sovereignty and public interests. The conflict of laws in this context represents a significant direction for future theoretical research and judicial practice development.

II. Which court has jurisdiction over foreign-related securities fraud litigation initiated in China?

China has established a system of centralized jurisdiction for civil lawsuits filed under the long-arm jurisdiction provisions of the Securities Law that is administered by the Beijing Financial Court, the Shanghai Financial Court, and the Chengdu-Chongqing Financial Court. The Supreme People's Court has respectively issued provisions regarding the jurisdiction of cases for each financial court[10]. The three financial courts coordinate jurisdiction among themselves by permitting the first court to docket a case to have jurisdiction. The Supreme People's Court has the right to settle any dispute over jurisdiction among the three courts[11].

[10] Article 2 of "Provisions of the Supreme People's Court on the Jurisdiction over Cases of the Beijing Financial Court", "Provisions of the Supreme People's Court on the Jurisdiction of the Shanghai Financial Court" and "Provisions of the Supreme People's Court on Cases under the Jurisdiction of the Chengdu-Chongqing Financial Court" each stipulate that the jurisdiction of the respective financial court includes lawsuits filed by "domestic investors on the ground that the securities offerings or trading or futures trading activities that occur outside the territory of the People's Republic of China infringe upon their lawful rights and interests" and lawsuits filed by "domestic individuals or institutions on the ground that the financial products sold or financial services provided by financial institutions outside the territory of the People's Republic of China infringe upon their lawful rights and interests".

[11] "Refining Jurisdiction over Cases and Fully Exercising Judicial Functions in Financial Matters: Q&A with the Head of the Second Civil Division of the Supreme People's Court on the Amendment to the 'Provisions of the Supreme People's Court on the Jurisdiction of the Shanghai Financial Court'": Regarding the coordination of jurisdiction between the Shanghai Financial Court and the Beijing Financial Court in such cases. Both the Shanghai Financial Court and the Beijing Financial Court have jurisdiction over financial disputes involving foreign companies that cause damage to domestic investors. This may give rise to jurisdictional conflicts, which means both the Beijing and Shanghai Financial Courts may claim jurisdiction over the same case. In fact, situations where two courts have jurisdiction over the same case are common in judicial practice. In this regard, Article 35 of the Civil Procedure Law provides that when two or more people's courts have jurisdiction over an action, the plaintiff may institute an action in one of such people's courts; and if the plaintiff institutes actions in two or more people's courts that have jurisdiction, the people's court which dockets the case first shall

In practice, instituting a civil action in a Chinese court may be subject to a jurisdictional dispute if the offering documents, transaction agreements, or other documents for a security contain explicit provisions regarding the jurisdiction for dispute resolution. We believe that Chinese courts will generally not exercise jurisdiction if there is a valid arbitration clause in the securities offering documents or transaction contracts. However, choice of dispute resolution forum for offering documents or transaction agreements for securities cannot necessarily preclude Chinese long-arm jurisdiction if the stipulated forum is a foreign court, or if the local laws of the jurisdiction where the securities are issued provide that disputes shall be subject to the jurisdiction of a specific court in that country. This is due to the nature of long-arm jurisdiction provisions as matters of national and public interest.

III. What procedural rules apply to foreign-related securities fraud litigation cases instituted in China?

Foreign-related securities litigation proceedings in China are governed by the Civil Procedure Law of the PRC and its judicial interpretations, in accordance with the principle that "procedural rules are governed by the law of the forum". The Civil Procedure Law will generally apply except for instances where its provisions may be modified by international treaties to which China has acceded.

Advantages of relying on Chinese long-arm jurisdiction under the Securities Law

China-concept stocks are key investment targets for Chinese investors looking to invest overseas, which are often structured through overseas holding companies. Securities violations committed by these overseas companies can directly damage the lawful rights and interests of numerous Chinese investors. These investors usually have clear and urgent needs to protect their rights in these cases, but the unique legal systems of the overseas jurisdiction and the high costs of cross-border claims pose significant obstacles to protecting their rights and seeking recovery.

Taking the Hong Kong Special Administrative Region as an example, Section 213 of the Securities and Futures Ordinance grants the Securities and Futures Commission the authority to take legal action on behalf of investors as a plaintiff. On this basis, with regard to securities fraud committed by listed companies, local judicial practice generally requires that civil litigation and other remedies be initiated primarily by securities regulators, who then work with the relevant parties to determine a compensation plan[12]. The legal framework for individual investor lawsuits is underdeveloped, and investors face exorbitant costs of legal recourse and considerable risk of an adverse judgment[13].

The "First Case of Extraterritorial Application of the Securities Law" of the Beijing Financial Court provides domestic investors with a potential means of recovery under Chinese law for overseas securities fraud.

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have jurisdiction over the action". Article 37, Paragraph 2 provides that where there is any dispute over jurisdiction between the people's courts, the dispute shall be resolved by the disputing courts through consultations; or if such consultations fail, the disputing courts shall request their common superior to specify jurisdiction. https://www.court.gov.cn/zixun/xiangqing/297961.html.

[12] See Shanghai Securities News: "PwC Agrees to Set Aside HK$1 Billion for Compensation over Evergrande's Financial Fraud", https://mp.weixin.qq.com/s/mMguhp1uGG14HPd9eUwVew.

[13] Christine Ruth Ong Chai Hoon v. Lam Kin Chung [2025] HKCFI 3857，legalref.judiciary.hk/lrs/common/ju/ju_frame.jsp?DIS=171891&currpage=T.

Compared to participating in an overseas proceeding, Chinese investors who institute a civil proceeding domestically under the Securities Law in connection with overseas securities fraud currently have at least three distinct advantages: policy support, a sound institutional framework, and cost-effectiveness. We address each of these advantages in turn.

First, these proceedings align with policy objectives. The judicial authorities have taken a clear stance and have already established a systematic institutional framework. The Beijing Financial Court has made clear in a statement in an exclusive interview with Legal Daily that it has established a systematic institutional framework for long-arm jurisdiction cases under the Securities Law. This move reflects that financial courts across the country intend to accept claims filed by domestic investors who have suffered losses due to overseas securities fraud in a manner consistent recent judicial policy pronouncements. Further, according to the interview, the court intends to explore the creation of a comprehensive dispute resolution mechanism encompassing "jurisdiction determination–model guidelines–bulk resolution", form specialized teams for foreign-related financial and securities matters, and build a professional financial judiciary.

Second, absent mandatory administrative procedures, the institutional framework and judicial practices governing investors' claims through civil litigation are relatively well-established. The current Several Provisions on False Securities Statements have abolished the previously existing preliminary administrative and criminal procedures and have established a civil dispute resolution pathway that does not rely on regulatory authorities. Investors do not need explicit guidance, support, or cooperation from regulatory authorities (whether domestic or foreign). Rather, investors may independently institute civil actions against listed companies, their actual controllers, directors, supervisors, and senior management, as well as intermediaries such as securities firms, and even other third parties complicit in the fraud. Particularly, in recent years, China's relevant judicial practices have continued to evolve and improve under the Several Provisions on False Securities Statements. China has now established a relatively robust civil compensation mechanism for securities fraud involving stocks, bonds, and even asset-backed securities, and has developed a comprehensive framework for determining the liability of issuers, intermediaries, and other parties. The financial courts have also accumulated extensive judicial experience in adjudicating relevant cases.

Third, domestic judicial procedures are highly efficient and cost-effective, offering better controllability over the overall process and expenses. Overseas litigation involves complex legal procedures such as determining jurisdiction, identifying applicable foreign laws, and notarizing and authenticating evidence. A full course of overseas litigation or arbitration proceedings can easily last three to five years or even longer. Coupled with the generally exorbitant and unpredictable legal fees in common law jurisdictions, investors face significant pressure from the high costs of dispute resolution. By comparison, instituting a civil action directly within China regarding securities fraud committed overseas would significantly reduce the costs associated with protecting investors' rights. In the "First Case of Extraterritorial Application of the Securities Law", the Beijing Financial Court efficiently facilitated a settlement between the parties and ensured its full implementation in less than two years, clearly demonstrating the distinct advantages of domestic judicial proceedings in terms of efficiency and cost-effectiveness. As noted in the Beijing Financial Court's case commentary, one of the institutional

functions of long-arm jurisdiction is that "[c]ross-border investors can bring lawsuits against foreign defendants in mainland courts, thereby reducing the complexity and costs of cross-border litigation and making it easier for investors to protect their rights and interests".

Concluding remarks

Effectively establishing and developing a system for the extraterritorial application of the Securities Law is an essential step towards leveraging advanced judicial capabilities to protect investors and provide judicial services to the international community. The Beijing Financial Court's ruling in the "First Case of Extraterritorial Application of the Securities Law" provides domestic investors with domestic remedies for overseas securities fraud. This means that even if Chinese investors purchase shares of overseas-listed companies, they can potentially institute actions in Chinese courts against those companies for securities fraud, making the "last mile" of protecting domestic investors' rights no longer out of reach. Chinese investors may take full advantage of China's policy support and institutional strengths to make active attempts, develop and leverage sophisticated judicial resources to safeguard their legitimate rights and interests, and advance the normalized development of the extraterritorial application of the Securities Law.

Important Announcement

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