Legal Commentary

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

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

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

Offshore R&D activities

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

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The 2026 Regulations stipulate that research data obtained overseas may be used for drug registration applications in China, provided that such data meets the relevant requirements of the NMPA. This principle dates back to October 2017, when the General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation in Drugs and Medical Devices (commonly known as "**Document No.42**"), which first proposed the acceptance of foreign clinical trial data for domestic registration. In July 2018, the Center for Drug Evaluation ("**CDE**") released specific technical guidelines to facilitate this process. The 2026 Regulations provides a stronger legal foundation for the acceptance of overseas data, thereby enabling the integration of global R&D resources and accelerating the development and market entry of innovative drugs.

The change of sponsor during IND phase

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

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

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

Change of IND sponsor to a different NDA applicant

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

Our practical experience indicates that companies must engage in detailed consultations with regulatory authorities prior to the NDA submission to confirm both the feasibility of a change in applicant and the specific procedural steps involved. Generally, applicants are required to submit explanatory materials characterized by clear logic and complete evidence to fully demonstrate compliance throughout the entire

process of transitioning from the clinical trial sponsor to a different entity as the NDA applicant. Furthermore, given the absence of explicit regulatory provisions, we strongly recommend maintaining close communication with the CDE to seek formal confirmation in practice.

Market exclusivity

As widely anticipated, the 2026 Regulations formally introduces a Market Exclusivity for orphan drugs and pediatric drugs for the first time in China. Specifically, it grants a protection period of up to seven (7) years for orphan drugs and up to two (2) years for pediatric drugs. During this exclusivity period, the NMPA will not approve the marketing of any identical drug products. Compared to the 2022 Draft, the 2026 Regulations have removed the provisions regarding first generic exclusivity. However, it is our understanding that the first generic exclusivity system was already established by the Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial) issued in 2021. Since the issuance of these Measures, pharmaceutical enterprises have successfully obtained 12-month first generic exclusivity periods. Following the established exclusivity system for generic drugs, this marks the official establishment of China's market exclusivity regime for orphan drugs and pediatric drugs.

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

Regulatory data protection

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

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

We note that the phrasing regarding the scope of drug protection in the 2026 Regulations is highly similar

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

Commercial sale of validation batches produced prior to regulatory approval

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

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

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

Segmented production of drugs

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

The 2026 Regulations formally establish the legal and operational framework for segmented drug production at the level of administrative regulations. Subject to the prerequisite of "demonstrated necessity", this provision limits the application of segmented production to specific types of drug products and emphasizes that it must be implemented under the unified responsibility of the MAH, subject to approval by regulatory authorities. This arrangement reflects the regulators' approach of providing

operational flexibility for production organization while strictly adhering to the principle of the MAH's comprehensive liability.

Regarding the scope of application, Article 32 of the 2026 Regulations not only covers innovative drugs with special requirements for production processes or facilities and equipment, but also explicitly includes clinically urgently needed drugs, drugs for responding to public health emergencies, and stockpile drugs. Furthermore, it provides a catch-all provision for "other drugs as stipulated by the drug supervision and administration department under the State Council", thereby leaving room for future institutional expansion. By comparison, Article 32 of the 2026 Regulations largely retains the provisions on segmented production from the 2022 Draft, stipulating that entrusted segmented production may be implemented for the aforementioned drug categories provided that the relevant requirements are met. Simultaneously, it incorporates the content regarding the segmented production of vaccines from the Provisions on the Supervision and Administration of Vaccine Production and Distribution (2022). It is stipulated that under specific circumstances where the production capacity of a Vaccine MAH is exceeded, the Vaccine MAH may, upon approval, entrust qualified vaccine manufacturers with the production or segmented production of vaccines. This provision thereby providing a higher-level legal basis for those specific vaccine regulations.

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

Online drug transactions responsibilities

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

According to the 2026 Regulations, if a third-party platform fails to establish a compliant online drug sales quality management system, or if an online drug transaction entity (including third-party platforms, MAHs, and drug distributors) provides information disclosure or hyperlink redirection services to other third parties (e.g., displaying drug information for other enterprises or redirecting clicks to external drug purchase pages)

in violation of drug supervision regulations, they shall be subject to administrative penalties. These penalties include orders for rectification, confiscation of illegal gains, or fines ranging from RMB 100,000 to RMB 2,000,000, depending on the severity of the circumstances. This update reflects the regulatory initiative to enforce the primary responsibilities of online drug transaction platforms and merchants while strengthening internal platform management.

It is evident that as online drug transaction activities evolve, the internet has become a critical channel for the public to access medicines. Consequently, the responsibilities of all parties involved are being progressively codified under drug supervision regulations, while key conduct issues in online transactions are now explicitly addressed at the legislative level.

Priority review and approval of drugs

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

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

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

Bundled review and approval system for active pharmaceutical ingredients

Since the issuance of the Measures for the Administration of Drug Registration (2020), China has fully implemented the bundled review and approval system for APIs. Under this system, a Notice of Approval is issued for chemical APIs that have passed the bundled review alongside the finished drug product. Notably, the 2026 Regulations stipulate the issuance of a Certificate of Approval for Chemical APIs, upgrading the terminology from "Notice" to "Certificate". This change formally enhances the authority of

the credential. Meanwhile, the 2026 Regulations further clarify and support the transfer of the API certificate, providing a clearer and more solid institutional foundation for the circulation and transaction of rights related to APIs.

Our understanding is that the 2026 Regulations do not alter China's existing bundled review and approval system for APIs. The provision allowing for the transfer of the Certificate of Approval for Chemical APIs aligns with the policy direction of "optimizing API management and lawfully changing API registration entities", as proposed in the Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Supervision to Promote High-Quality Development of the Pharmaceutical Industry ([2024] No. 53). Given the current lack of detailed implementation measures, the specific operational path for such transfers remains to be clarified by subsequent supporting rules and warrants continuous attention.

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

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

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

MAH domestic responsible persons

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

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

lacks a supporting quality and risk control system will find it difficult to meet the qualification requirements under the new regulatory regime.

Meanwhile, the 2026 Regulations echo Article 7 of the Provisional Administrative Measures for the Designation of Domestic Responsible Persons by Overseas Marketing Authorization Holders (Announcement No.137, 2024), adding a new requirement that "the relevant information of the designated domestic legal entity must be stated in the drug package insert". (For more information regarding Announcement No.137, please refer to our article: *Strengthening Oversight of Imported Drugs: Key Takeaways into New Regulations on Domestic Responsible Entities (Bilingual)*) This provision means that domestic responsible persons will not only be subject to regulatory inspections but will also directly face patients and the public, further strengthening their legal status as the responsible entities within China. Therefore, we recommend that when searching for and designating a domestic MAH agent, overseas enterprises should focus on auditing the agent's qualifications and capabilities to ensure that they possess a compliance system capable of substantively undertaking statutory responsibilities.

Accessible drug labels and package inserts

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

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

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

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

Compared to the 2002 Regulations, the 2026 Regulations introduce new provisions stipulating that the personal carrying or mailing of small quantities of drugs into China shall be limited to reasonable quantities

for self-use and must comply with national regulations governing the entry of personal effects. This requirement generally maintains the regulatory approach of the 2022 Draft. The author believes that under the current policy framework, there remains a certain degree of policy leeway for cross-border e-commerce platforms to conduct retail drug import business. However, the compliance boundaries and regulatory interpretations in this area warrant continuous attention to policy trends and the evolution of enforcement practices.

Counterfeit and substandard drugs

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

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

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

Statutory time limits for administrative approval

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

For the first time at the administrative regulation level, the 2026 Regulations stipulate that the time required for technical review involved in applications for drug registration, GLP laboratory qualifications, drug

manufacturing licenses, drug distribution licenses, and medical institution preparation licenses, shall not be counted towards the statutory time limits for administrative licensing. By consolidating previously scattered rules, the Regulations provide applicants with clearer legal expectations regarding review and approval timelines, while simultaneously ensuring that regulatory authorities have the necessary time to conduct rigorous technical evaluations.

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

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

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

Legal liability

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

Conclusion

Overall, the 2026 Regulations mark a new stage of maturity for China's drug regulatory system. Building on the achievements of the MAH system and reforms in the review and approval process, the 2026 Regulations demonstrate a forward-looking and sophisticated approach by actively addressing industry concerns such as market exclusivity, data protection, fragmented production, importation of clinically

urgently needed drugs and online drug sales. Naturally, the operational details of certain provisions still require further clarification through supporting rules. We look forward to the prompt issuance of relevant guidelines by regulatory authorities to ensure smooth and effective implementation that fully unlocks the potential of these new policies. Moving forward, we will continue to monitor all developments closely to provide our clients with timely and expert legal support.

Important Announcement

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

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