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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

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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 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.

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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