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Analysis of China's New Draft of Drug Regulatory Data Protection Rule: A New Perspective on Innovative Drug Transactions

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On March 19, 2025, the Comprehensive Department of the National Medical Products Administration released the *Measures for the Implementation of Drug Regulatory Data Protection (Trial, Draft for Comments)* and the *Procedures for Drug Regulatory Data Protection (Draft for Comments)* (collectively referred to as the "**Draft for Comments**"). As an important mechanism for promoting pharmaceutical innovation, the drug regulatory data protection system, operating in parallel with the patent linkage system, is expected to have a significant impact on the marketing of New Drugs and drug licensing transactions once effectively implemented. This article provides a brief analysis of the drug regulatory data protection system and its implications for pharmaceutical industry.

Drug regulatory data protection system in China

I. Background and Introduction

Drug regulatory data protection (the "**RDP**") refers to the protection granted by the National Medical Products Administration (the "**NMPA**") over trial data and other data submitted by applicants that were independently obtained and not publicly disclosed at the time of marketing approval for new chemical entities or other pharmaceuticals specified in the Draft for Comments (collectively referred to as the "**New Drugs**"). Without the consent of the original applicant, other applicants may not rely on these data to seek marketing authorization or supplementary applications (referred to as the "**RDP system**").

As early as 2002, the *Regulations for the Implementation of the Drug Administration Law (2002)* issued by the State Council established general provisions for China's RDP system, which have been retained in the current effective *Regulations for the Implementation of the Drug Administration Law (2024)*. However, due to the long-standing absence of detailed operational rules, the system had not been fully implemented. In 2018, the NMPA released the *Measures for the Implementation of Drug Regulatory Data Protection (Provisional) (Draft for Comments)*, setting out more detailed provisions for the practical implementation of the RDP system, though it was never formally enacted. In 2025, the

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NMPA issued a new Draft for Comments, further refining and improving the RDP system. The key updates in the 2025 version are summarized as follows:

- Protected subjects: in addition to innovative drugs and improved new drugs, the scope of protection extends to first generic drugs, with all three categories covering chemical drugs and biological products, contributing to a more balanced approach between encouraging innovation and promoting generics.
- Protection period: the protection period for innovative drugs is uniformly set at six years, with improved new drugs and first generic drugs each receiving three years of protection; for drugs already marketed overseas but not yet approved in China ("**drugs marketed overseas but not yet marketed domestically**"), a time-differential-based calculation method has been introduced: the protection period is calculated as six years (for innovative drugs) or three years (for improved new drugs) minus the interval between the date of first overseas marketing approval and the date of domestic application acceptance, which aims to incentivize earlier registration and market entry of drugs in China.
- Protection mechanism: during the data protection period, marketing applications for (other) generic drugs that have not yet been marketed will not be approved (unless exceptions specified in the Draft for Comments apply). However, to provide predictability for industry stakeholders, such applications may be accepted within one year before the expiration of the protection period.

II. RDP and patent linkage system

To encourage new drug research and development and promote the advancement of high-quality generic drugs, China has established a unique drug patent linkage system in recent years. This system aims to address patent disputes at an early stage of the drug registration process by linking the review and approval of generic drug with the resolution of related patent conflicts. The final implementation of the RDP system is expected to complement the traditional patent linkage system, jointly protecting drug innovation while enhancing the predictability of generic drug market entry.

First, the two systems have different applicable subjects. The patent linkage system primarily applies to patents registered on the China Marketed Drug Patent Information Registration Platform, providing an effective platform for pharmaceutical companies to protect intellectual property and to resolve drug patent disputes at an early stage. In contrast, the RDP system focuses on the protection of trial data and other data, thereby securing a period of market exclusivity for New Drugs. These two systems jointly establish a comprehensive framework for protecting pharmaceutical innovation.

Second, the two systems are complementary in terms of effectiveness. The implementation of the patent linkage system is based on valid patent rights, which may be subject to expiration or judicial proceedings or administrative rulings that could result in invalidation or expiration, thereby affecting the feasibility and practical effectiveness of the patent linkage system. Moreover, the judicial and administrative processes under the patent linkage system can be lengthy and costly, potentially impacting the commercialization of marketed drugs. In this regard, the RDP system can serve as a valuable complement. For example, RDP is directly granted by the NMPA based on the registration

classification of marketed drugs, and such protection can be obtained without any judicial proceedings or administrative rulings, allowing for a more predictable and stable delay in the marketing of other generic drugs, thereby enhancing the stability and predictability of market returns.

However, questions remain regarding the harmonization and practical implementation of the patent linkage system and the RDP system. For instance, if the current text of the Draft for Comments is finalized, it is still unclear whether patent linkage procedures (such as judicial proceedings or administrative rulings initiated by patent holders) shall await the final year of the data protection period before being initiated.

2025 Draft for Comments: implications for licensing transactions

For both licensors and licensees, understanding the potential impact of the RDP system on licensing transactions and proactively structuring deal arrangements are essential to effectively manage risks and optimize returns. To this end, this section explores the implications of the Draft for Comments on licensing agreements focusing on two key areas: contractual clause design and transactional strategy:

I. From the perspective of contractual clause design

- Regulatory Exclusivity

The royalty term is closely related to the term of the license agreement and is typically determined by the earliest or latest of the following three events: (1) the expiration of the last-to-expire patent right (Last Valid Claim); (2) a certain period after the first commercial sale of the licensed product; and (3) the expiration of all Regulatory Exclusivity. In past drug licensing transactions in Chinese mainland, although Regulatory Exclusivity (such as RDP) was often incorporated into agreements, its practical effect was usually limited, as the RDP system had not yet been implemented.

If the Draft for Comments is eventually implemented, the relevant provisions are expected to have practical impact in the future and could generate significant commercial benefits for licensors. In particular, when the royalty term is set to expire at the latest of the aforementioned three specified events, and the patent protection period has expired but the RDP remains in effect, both parties of the licensing transaction shall assess such scenario based on their commercial arrangements. From the licensor's perspective, the implementation of the RDP system could potentially extend the royalty term, allowing for higher royalty payments; thus, the licensor should seek to include the Regulatory Exclusivity as a factor in calculating the royalty term. From the licensee's perspective, to mitigate the impact of the Regulatory Exclusivity, it may seek to set the earliest of the three specified events as the end date of the royalty term.

In addition, the Regulatory Exclusivity may also affect royalty adjustments. In licensing transactions, royalties are typically subject to reduction for certain circumstances, such as the expiration of the Last Valid Claim or the market entry of a generic drug. As a result, both parties of a licensing transaction should carefully assess the potential timing of generic entry and its commercial impact on royalty payments.

- Drug development and market entry plan

The sequence in which the same licensed product is marketed in different regions often affects its applicable registration classification in Chinese mainland. According to the current Draft for Comments, different registration categories are associated with varying RDP periods, which requires both the licensor and licensee to take into account the commercial implications of the RDP system and align on a coordinated global market entry strategy for the licensed product.

For example, in the case of a chemical drug transaction, if the licensee intends for the licensed product to qualify as a Class 1 innovative drug (eligible for a 6-year RDP period) in China, it should coordinate with the licensor on the global development and marketing timeline to ensure that the licensor does not obtain NDA approval in the United States (or in other jurisdictions) before the licensee submits the NDA in China, a critical step in securing the Class 1 innovative drug status in China. Alternatively, if the licensee intends to register the licensed product as a Class 5.1 chemical drug, it is advisable to align with the licensor on the timing of domestic and overseas market entry. For Class 5.1 chemical drugs, the RDP period is determined by the length of interval between the date of first overseas marketing approval and the date of domestic application acceptance; if the product is marketed overseas too early and the Chinese NDA submission is significantly delayed, the licensed product may fail to qualify for an adequate RDP period.

- Diligence obligations and responsibilities of the parties

Given the commercial impact and practical implementation of the RDP system, obtaining a specific registration status (e.g., first generic drug under Class 3 or 5.2) often requires strict adherence to regulatory timelines and procedural requirements. In such cases, both parties and related collaborators (e.g., CROs, CDMOs) may clearly define timelines, task allocations, and diligence obligations in relevant agreements. This helps align expectations and reduce the risk of potential disputes arising from inconsistent timelines or unclear responsibilities.

For example, between the licensor and licensee, the agreement may specify which party is responsible for applying for marketing approval and RDP, how associated costs will be borne, and the rights and obligations of all parties during the pre-marketing application and review period. It may also set out provision regarding liabilities in case RDP is not obtained. Additionally, to ensure timely awareness of the formal implementation of the RDP system, it may be agreed that one party shall immediately notify the other upon confirming the feasibility of the RDP and submit it to JxC for discussion on application strategy.

II. From the perspective of transactional strategy

- Re-evaluate financial terms

If the Draft for Comments is effectively implemented, the market exclusivity of brand-name drugs and certain generic drugs will be potentially prolonged under the RDP system, thereby affecting drug pricing and market revenue. Specifically, the extended market exclusivity period for New Drugs may enhance the predictability of cash flows after product marketing. As a result, the parties of a licensing transaction should factor the value of the RDP system into structuring financial terms, including upfront

payments, milestone payments, and royalty rates, and adjust accordingly.

- Schedule simultaneous/early marketing of drug in China

According to the Draft for Comments, for drugs marketed overseas but not yet marketed domestically, the shorter the interval between the date of first overseas marketing approval and the date of domestic application acceptance, the longer the potential data protection period available domestically. Therefore, brand-name drug licensors and licensees should consider early planning—for example, domestic licensees may seek to introduce brand-name drugs to the Chinese market at an earlier stage, while overseas licensors may aim to find Chinese partners as early as possible; from the perspective of generic drug companies, they may also accelerate R&D timelines to secure regulatory approval prior to the domestic marketing of the brand-name drug, thereby obtaining an adequate RDP.

- Exploring the transactional value of data

The Draft for Comments does not prohibit other applicants from using trial data and other data with the consent of the rights holder. As a result, brand-name drug companies or first generic drug companies may potentially generate revenue by authorizing other pharmaceutical companies to use the relevant data, thereby maximizing the economic value of such data and enhancing the revenue potential of the drug. However, the feasibility of licensing trial data remains subject to further clarification by the regulatory authorities.

Overall, compared to the *Measures for the Implementation of Drug Regulatory Data Protection (Provisional) (Draft for Comments) (2018)*, the Draft for Comments expands the scope of protected pharmaceuticals to include innovative drugs, improved new drugs, and first generic drugs (all of which include chemical drugs and biological products). For different indications of an innovative drug under a single approval number, RDP can be granted according to the respective registration categories, without separate distinction for each indication. This means that when designing and structuring future transactions, parties of a licensing transaction can further consider, from their individual perspectives, the potential opportunities and favorable impacts arising from the RDP system.

Outlook

At present, the *Drug Administration Law* does not contain provisions on RDP, which is only reflected in the *Regulations for the Implementation of the Drug Administration Law*. If the Draft for Comments is formally implemented, brand-name drug companies will be better positioned to leverage the RDP system to strengthen the protection of innovative products and formulate forward-looking market strategies for the China market. At the same time, generic drug companies can also benefit from the market exclusivity period offered by RDP system for first generic drugs to strategically plan their regulatory submission timelines, while exploring collaboration opportunities with brand-name drug companies. The release of this Draft for Comments signals that China is steadily establishing a more systematic framework for the protection of pharmaceutical innovation. We believe that the coordinated development of the patent linkage system and the RDP system will further refine the legal balance between innovation incentives and generic drug development, ultimately driving China's pharmaceutical industry toward higher-quality and sustainable growth.

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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