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China's Drug Market Exclusivity Regime: Recent Regulatory Developments and Market Implications

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On October 19, 2026, the National Medical Products Administration (NMPA) released the *Measures for the Implementation of Drug Market Exclusivity (Draft for Comments)* (the "Draft Measures"), soliciting public comments on the scope of application, protection periods, application procedures, coordination with other regulatory regimes, and termination mechanisms for market exclusivity applicable to drugs for the treatment of rare diseases and pediatric drugs. The deadline for submitting comments is November 18, 2026.

The Draft Measures further elaborate on Article 21 of the newly revised *Regulations for Implementation of the Drug Administration Law of the People's Republic of China* (the "Implementing Regulations"), which came into effect on May 15, 2026. Rather than establishing China's drug market exclusivity regime for the first time, the Draft Measures further clarify the specific eligibility criteria and implementation rules based on the existing market exclusivity mechanism for first generic drugs and the newly established market exclusivity regimes for pediatric drugs and drugs for the treatment of rare diseases. These developments will not only affect incentives for pharmaceutical research and development (R&D), but also influence drug registration strategies, competitive dynamics between innovative and generic drugs, and intellectual property (IP) strategies and business transactions in the pharmaceutical sector.

China's Existing Drug Market Exclusivity Regime

I. Regulatory Framework for Market Exclusivity

China's pharmaceutical protection framework encompasses market exclusivity, drug test data protection, pharmaceutical patent protection, and protection of traditional Chinese medicine (TCM) varieties. These regimes differ in their subject matter, eligibility requirements, and legal effects.

With respect to market exclusivity, China previously established a market exclusivity mechanism for first generic drugs under the *Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim)*. Article 11 of these Measures provides that the first chemical generic drug to successfully challenge a patent and obtain marketing approval shall be granted a 12-

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month market exclusivity period. During this period, marketing approval will generally not be granted to other generic drugs of the same type, except for those that successfully challenged the patent jointly. Moreover, the exclusivity period may not extend beyond the term of the original patent covering the challenged drug. This mechanism aims to encourage generic pharmaceutical companies to engage in patent challenges and promote competition in the pharmaceutical market by rewarding eligible first successful patent challengers.

The Implementing Regulations, as revised in 2026, further extend market exclusivity to pediatric drugs and drugs for the treatment of rare diseases. Under Article 21, eligible new varieties of pediatric drugs, pediatric drugs with new dosage forms or strengths, and drugs with newly added pediatric indications may be granted market exclusivity for a period not exceeding two years. Eligible drugs for the treatment of rare diseases may be granted market exclusivity for a period not exceeding seven years, provided that the marketing authorization holder (MAH) undertakes to ensure a continuous supply of the drug. If the MAH fails to fulfill its supply assurance undertaking, the market exclusivity period shall be terminated.

Accordingly, China has gradually developed a differentiated market exclusivity incentive framework covering first generic drugs, drugs for the treatment of rare diseases, and pediatric drugs. The first generic drug mechanism primarily seeks to encourage patent challenges and generic drug competition, whereas market exclusivity for pediatric drugs and drugs for rare diseases focuses on addressing insufficient R&D incentives in specific therapeutic areas.

II. Distinctions Between Market Exclusivity and Other Pharmaceutical Protection Regimes

Market exclusivity is not an extension of pharmaceutical patent rights, but rather a form of administrative protection within the drug registration and regulatory framework. Its principal function is to restrict other applicants from obtaining marketing approval for drugs of the same type within the protected scope during a prescribed period, thereby providing eligible drugs with a degree of competitive advantage in the market.

Unlike market exclusivity, drug test data protection primarily covers undisclosed test data and other data independently generated by an MAH. It restricts other applicants from relying on such protected data without authorization when applying for drug registration, but does not necessarily prevent competitors from seeking marketing approval based on independently generated data. Pharmaceutical patent protection, by contrast, is based on valid patent rights and restricts unauthorized exploitation of technical solutions falling within the scope of the patent claims. In addition, the protection regime for TCM varieties has its own independent eligibility requirements and legal effects.

Therefore, market exclusivity periods, test data protection periods, and patent protection terms cannot simply be equated with one another, nor are they necessarily cumulative. The competitive protection window for a particular drug must be assessed comprehensively by reference to its registration classification, eligibility for market exclusivity, applicable test data protection, valid patents, and other relevant regulatory regimes.

Article 21 of the Implementing Regulations has already established the basic framework for market exclusivity applicable to pediatric drugs and drugs for the treatment of rare diseases. However, specific eligibility criteria, protection periods, application procedures, commencement dates, the handling of registration applications for drugs of the same type, and termination mechanisms have remained subject to further implementing rules. Against this background, the Draft Measures further elaborate on the existing framework.

Major Regulatory Changes Under the Draft Measures

Previously, the Implementing Regulations principally prescribed the categories of drugs eligible for market exclusivity and the maximum protection periods, without specifying detailed eligibility criteria, application procedures, or mechanisms for coordinating different pharmaceutical protection regimes. The Draft Measures provide further clarification in the following respects.

Item	Article 21 of the Existing Implementing Regulations	October 2026 Draft Measures	Nature of Change
Exclusivity period for rare disease drugs	Not exceeding 7 years	Differentiated periods of 7, 5, or 4 years according to drug type	Specification of detailed criteria
Exclusivity period for pediatric drugs	Not exceeding 2 years	Differentiated periods of 2 or 1 year	Specification of detailed criteria
Identification of rare diseases	No specific scope prescribed	Based on the national rare disease catalog, while allowing eligible drugs for diseases not included in the catalog to qualify	Clarification and expansion of eligibility pathways
Identification of pediatric drugs	Lists new drug varieties, new dosage forms, new strengths, and newly added pediatric indications	Specifies eligibility criteria relating to pediatric indications, therapeutic functions, or dosage and administration	Clarification of eligibility requirements
Drugs already marketed overseas	No detailed differentiation	Expressly covers certain overseas-marketed originator drugs, improved new drugs, and other eligible drugs	Further specification of eligible drug categories
Commencement of the exclusivity period	No specific commencement rule	Market exclusivity for rare disease drugs generally commences on the date of marketing approval	New commencement rule

Item	Article 21 of the Existing Implementing Regulations	October 2026 Draft Measures	Nature of Change
Coordination with data protection periods	Not specified	Market exclusivity for eligible pediatric drugs may commence after expiration of the applicable data protection period	Significant regulatory innovation
Different indications	Not specified	Exclusivity periods granted successively for different indications are calculated separately	New calculation rule
Multiple applications	Not specified	Only one market exclusivity period may be sought under the same drug registration application	New restriction
Termination conditions	Provides for termination where the MAH fails to fulfill its supply assurance undertaking for rare disease drugs	Further specifies termination circumstances, including public health emergencies, and addresses revocation mechanisms	Further elaboration of exit mechanisms

I. Clarifying the Scope of Application and Eligibility Criteria and Establishing an Application Pathway for Drugs Targeting Rare Diseases Outside the National Catalog

The Draft Measures further clarify the eligibility requirements for drugs intended to treat rare diseases and pediatric drugs, and define "drugs of the same type" to delineate the scope of market exclusivity.

For rare disease drugs, the proposed rules cover not only drugs whose labeled indications or therapeutic functions include, or fall within the scope of, rare diseases listed in the *Catalog of Rare Disease* issued by the National Health Commission, but also allow drugs for diseases not included in the catalog to apply for market exclusivity if they meet the relevant requirements following expert assessment. For diseases outside the catalog, the assessment must consider factors such as disease incidence or prevalence, disease severity, available treatment options, and the additional clinical benefits offered by the drug. The significance of this arrangement lies in the fact that eligibility for market exclusivity would no longer be entirely confined to the existing rare disease catalog. For diseases that have not yet been included in the catalog but present substantial unmet clinical needs, eligible therapeutic drugs may also benefit from market exclusivity incentives, thereby creating new regulatory expectations for pharmaceutical R&D and the introduction of innovative drugs from overseas.

For pediatric drugs, the Draft Measures propose requiring that the drug be developed for pediatric populations and that its prescribing information specify pediatric indications, therapeutic functions, or pediatric dosage and administration. In addition, the proposed rules clarify the criteria for determining

whether drugs are of the "same type," taking into account factors including the generic name, active ingredient or TCM prescription, dosage form, and indications or therapeutic functions. Where market exclusivity is sought for a new strength of a pediatric drug, whether the strengths are identical must also be considered. These criteria help determine the actual scope of drugs covered by market exclusivity and avoid classifying drugs as being of the same or different types solely on the basis of similarities or differences in their names.

II. Refining General Maximum Exclusivity Periods into Differentiated Protection Periods

The Implementing Regulations provide for market exclusivity periods of no more than seven years for drugs for the treatment of rare diseases and no more than two years for pediatric drugs. The Draft Measures further establish differentiated protection periods according to drug type and registration circumstances, as summarized below.

Drug Category	Applicable Circumstances	Proposed Exclusivity Period
Rare disease drugs	Innovative drugs and overseas-marketed originator drugs obtaining marketing approval in China	7 years
	Eligible improved new drugs	5 years
	Eligible generic drugs or biological products already marketed overseas and obtaining marketing approval in China for the first time, or the first addition of rare disease indications already approved overseas, among other circumstances	4 years
Pediatric drugs	Innovative drugs and overseas-marketed originator drugs obtaining marketing approval in China	2 years
	The first addition of pediatric indications to already marketed drugs, or new dosage forms or strengths of pediatric drugs	1 year

For eligible rare disease drugs, the proposed rules would grant market exclusivity periods of seven, five, or four years, respectively, depending on whether the drug is an innovative drug or an overseas-marketed originator drug obtaining marketing approval in China, an improved new drug, or an eligible overseas-marketed generic drug or biological product obtaining marketing approval in China for the first time, or a drug to which a rare disease indication already approved overseas is added for the first time, among other circumstances.

For pediatric drugs, a two-year market exclusivity period is proposed for innovative drugs and overseas-marketed originator drugs obtaining marketing approval in China. A one-year market exclusivity period would apply where a pediatric indication is added to an already marketed drug in China for the first time, or where a new dosage form or strength is introduced for a pediatric drug, among other circumstances.

III. Clarifying the Commencement of Market Exclusivity and Its Coordination with Test Data Protection Periods

The Draft Measures further specify the commencement dates of market exclusivity periods. For drugs intended to treat rare diseases, market exclusivity would commence on the date of marketing approval and may run concurrently with any applicable drug test data protection period.

A different arrangement is proposed for pediatric drugs. Where no drug test data protection period has been granted, market exclusivity would commence on the date of marketing approval. Where a drug has already been granted, or is simultaneously granted, a drug test data protection period, market exclusivity would be added after the corresponding data protection period and would commence on the day following its expiration.

This coordination mechanism represents a significant regulatory change introduced by the Draft Measures. For example, where an eligible innovative pediatric drug is granted a six-year test data protection period and a two-year market exclusivity period, and both protections apply without any other special circumstances, the market exclusivity period may commence immediately after the data protection period expires, creating a sequential arrangement of administrative protections.

Nevertheless, the legal effects of the two forms of protection remain distinct. Data protection primarily restricts unauthorized reliance on protected data in drug registration applications and does not necessarily prevent other applicants from seeking marketing approval based on independently generated data. Market exclusivity, by contrast, imposes additional restrictions on the marketing approval of drugs of the same type within the protected scope. From the perspective of competitive protection or market protection, market exclusivity provides stronger protection than data protection, because even if a competing company independently completes clinical trials and obtains marketing approval, thereby circumventing the restrictions associated with data protection, it would still be prohibited from selling the drug if subject to market exclusivity. Accordingly, when assessing a product's competitive protection window, companies should separately verify the eligibility requirements, protection periods, and implementation mechanisms of the two regimes, rather than simply adding together their respective statutory maximum periods.

IV. Establishing Application Procedures and the "One Exclusivity Period" Principle

The Draft Measures propose that applicants must submit an application for market exclusivity concurrently with their drug registration application. Supplementary applications for market exclusivity would not be permitted after the drug has obtained marketing approval. The Center for Drug Evaluation (CDE) would assess eligibility for market exclusivity as part of the drug registration review process. Where the eligibility requirements are satisfied, the commencement and expiration dates of the market exclusivity period would be recorded in the drug approval documentation and publicly disclosed through official channels.

At the same time, the proposed rules establish the "one exclusivity period" principle, under which an applicant may apply for only one market exclusivity period in respect of the same drug registration application. Where a drug simultaneously satisfies the eligibility requirements for both rare disease

drug and pediatric drug protection, the applicant must select one of the two categories when applying. However, where market exclusivity is granted successively for different indications of the same drug, the exclusivity period for each indication is calculated separately.

V. Clarifying the Rules Governing Registration Applications, Technical Review, and Marketing Approval of Competing Drugs During the Exclusivity Period

The Draft Measures further elaborate on the rules governing the registration of drugs of the same type during an applicable market exclusivity period. Under the proposed arrangements, other drugs of the same type may undergo registration application procedures and technical review in accordance with the law. However, marketing approval generally may not be granted until the relevant market exclusivity period has expired, and such drugs must satisfy the technical requirements applicable at the time of approval.

This arrangement distinguishes between technical review of drug registration applications and final marketing approval. Market exclusivity does not mean that competing drugs are entirely prohibited from undergoing R&D or registration review; rather, it primarily restricts their ability to obtain marketing approval during the protection period.

For innovative pharmaceutical companies, this arrangement helps enhance the predictability of market competition for eligible products. For generic drug and biological product developers, it means that, in addition to monitoring patent terms and test data protection periods, they should also examine whether relevant products may qualify for market exclusivity, the scope of such exclusivity, and its expiration date when making project initiation and drug registration plans, so as to reasonably schedule R&D investment and regulatory submissions.

VI. Improving Coordination with the Protection Regime for Traditional Chinese Medicine Varieties

The Draft Measures propose clarifying that TCM varieties already granted market exclusivity may apply for protection as TCM varieties in accordance with the law during the market exclusivity period, thereby providing a pathway for eligible TCM products to benefit from coordination between different protection regimes.

Market exclusivity and protection of TCM varieties have different legal bases and eligibility requirements and do not constitute the same regulatory regime. Whether a particular TCM variety may benefit from both forms of protection remains subject to separately satisfying the statutory requirements of each regime. The grant of market exclusivity does not automatically establish eligibility for protection as a TCM variety.

This arrangement provides a clearer pathway for coordinating different protection regimes applicable to eligible innovative TCM products. However, the specific protective effects must still be assessed in light of the respective scopes of application and implementing rules.

VII. Refining the Mechanisms for Termination, Revocation, and Supply Assurance

The Implementing Regulations already establish assurance of market supply as a prerequisite for rare disease drugs to obtain market exclusivity and provide that market exclusivity shall terminate if the

MAH fails to fulfill its supply assurance undertaking. The Draft Measures further specify supply assurance requirements, proposing that applicants make a supply assurance undertaking when applying for market exclusivity and, except in cases of force majeure, avoid production suspension or supply interruption. Where a potential drug shortage risk is identified, the applicant should report it to the relevant authorities in advance.

With respect to exit mechanisms, the Draft Measures further specify how market exclusivity should be handled in circumstances including the revocation, withdrawal, or cancellation of a drug registration certificate, failure by the MAH to fulfill its supply assurance undertaking, and the occurrence of a public health emergency accompanied by a request from the relevant competent authority. These provisions concern the termination and revocation of market exclusivity.

These arrangements demonstrate that market exclusivity is not an unconditional, fixed commercial benefit granted to pharmaceutical companies, but an administrative protection measure linked to continuous drug supply and public health interests. For rare disease drugs, companies must continue to fulfill their supply assurance obligations after obtaining market exclusivity. They cannot merely secure market protection without ensuring patients' access to medicines and continuity of treatment.

Implications of the Draft Measures for the Pharmaceutical Industry and Related Legal Practice

I. Enhancing Commercial Predictability for Pediatric and Rare Disease Drug Development

Differentiated exclusivity periods and clearer eligibility criteria will help companies assess potential administrative protection periods at the R&D project initiation stage and incorporate them into calculations of R&D investment, product pricing, and investment returns. The establishment of an application pathway for drugs targeting rare diseases outside the national catalog also creates new regulatory expectations for R&D projects intended to address unmet clinical needs.

For pediatric drugs, the inclusion of newly added pediatric indications, new dosage forms, and new strengths within the proposed scope of protection means that the value of pediatric drug development need not depend entirely on the discovery of novel active ingredients. The development of pediatric applications for already marketed drugs may also qualify for corresponding market exclusivity incentives.

However, such protection remains conditional upon satisfaction of the applicable eligibility requirements. Companies cannot assume that a product is entitled to a particular exclusivity period solely because it falls within the category of pediatric drugs or drugs for the treatment of rare diseases.

II. Reshaping the Competitive Timelines of Innovative and Generic Drugs

Market exclusivity directly affects the earliest date on which eligible competing drugs of the same type may obtain marketing approval. For innovative pharmaceutical companies, clearly defined exclusivity periods and the mechanism for coordinating market exclusivity with pediatric drug data protection may further strengthen expectations regarding commercial protection. For generic drug and biological product companies, market exclusivity must be incorporated into competitive product analysis and

drug registration timelines.

In particular, where product patents are approaching expiration and the relevant test data protection periods are nearing their end, market exclusivity may become an important factor in determining when competing drugs can enter the market. Companies should separately assess whether the relevant patents remain valid, whether the products and technologies concerned fall within the scope of the patent claims, whether test data protection applies, and whether market exclusivity covers the proposed drug registration application. Different protection regimes should not be conflated.

III. Implications for Pharmaceutical BD Transaction Valuations and Contractual Risk Allocation

In pharmaceutical license-in/license-out and co-development transactions, market exclusivity may become an important factor affecting the commercial value of a product. In addition to reviewing patent ownership, remaining patent terms, freedom-to-operate risks, test data protection, and regulatory approval progress, transaction parties should also examine whether the target product satisfies the eligibility requirements for market exclusivity, the anticipated protection period, the applicable indications, the progress of the exclusivity application, and the risk of early termination.

More specifically, in business development (BD) agreements, these factors will directly affect the contractual determination of the Royalty Term. Generally, the calculation of a Royalty Term is anchored to three factors: valid claims of licensed patents, the commercial sales lifecycle, and the period of administrative protection or regulatory exclusivity (Regulatory Exclusivity Period). Administrative protection or regulatory exclusivity, including market exclusivity, is an important consideration. In particular, the newly proposed rules allowing market exclusivity for eligible pediatric drugs to commence after the expiration of the data protection period, and allowing exclusivity periods granted successively for different indications to be calculated separately, are both likely to influence how transaction parties structure the Royalty Term.

For products involving both pediatric and rare disease indications, transaction parties should also assess the implications of the “one exclusivity period” rule for drug registration strategies and protection periods, and structure milestone payments, revenue-sharing arrangements, and commercialization provisions in light of the development timelines for different indications.

For rare disease drugs, supply assurance obligations will also become an important contractual risk factor. Transaction parties should clearly allocate responsibilities relating to manufacturing, active pharmaceutical ingredient (API) supply, minimum inventory levels, shortage warnings, and supply interruptions, and appropriately structure continuing supply obligations and liability for breach of contract. Although contracts may allocate performance obligations and economic risks between the parties, contractual arrangements cannot alter the legally designated responsible entity as determined by the regulatory authorities.

Conclusion

The Measures for the Implementation of Drug Market Exclusivity (Draft for Comments) do not establish China’s drug market exclusivity regime anew. Rather, they systematically elaborate on the framework for

market exclusivity applicable to pediatric drugs and drugs for the treatment of rare diseases under the Implementing Regulations, while further clarifying its relationship with the existing market exclusivity mechanism for first generic drugs and other pharmaceutical protection regimes.

The principal changes include clarifying the scope of eligible drugs and applicable eligibility criteria, establishing differentiated exclusivity periods, prescribing application procedures and commencement rules, clarifying coordination with test data protection periods, and improving the regulatory approval rules for competing drugs during the exclusivity period and the mechanisms for terminating protection.

Overall, China's pharmaceutical protection framework is evolving into a multi-layered system founded on patent protection, supplemented by test data protection and market exclusivity, and operating alongside other regimes such as protection of TCM varieties. For pharmaceutical R&D companies and parties involved in related transactions, future strategies will need to go beyond patent portfolio management and regulatory approval timelines to incorporate various regulatory exclusivity regimes and their implications into R&D planning, competitive analysis, and transactional due diligence.

Note: As of October 20, 2026, the Draft Measures have not yet been formally implemented. The relevant rules and their specific application remain subject to the final officially promulgated measures.

Important Announcement

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