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China Releases Draft Implementation Measures for the Protection of Drug Trial Data Including Data Exclusivity for Foreign-Originated Drugs

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On March 19, 2025, China's National Medical Products Administration (NMPA) released Implementation Measures for the Protection of Drug Trial Data (Trial, Draft for Comments) (????????????(????????))and Working Procedures for the Protection of Drug Trial Data (Draft for Comments) (????????????(?????)) that provides up to 6 years of data exclusivity of clinical trial data required to be submitted to the NMPA to prove safety and efficacy of a new drug to prevent generic drug manufacturers from relying on this data in their own applications. In contrast, the US generally provides 5 years of exclusivity. However, for foreign-originated drugs, the Chinese data protection period will be 6 years minus the time difference between the date on which the drug's marketing authorization application in China is accepted and the date on which the drug first obtains marketing authorization overseas. Comments are due before May 18, 2025. The original documents as well as spreadsheets to submit comments are available here (Chinese only).

A translation of the Implementation Measures follows.

Article 1 (Purpose and Basis) These Measures are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Drug Registration Management Measures and other relevant regulations in order to encourage drug innovation and meet the public's demand for medicines.

Article 2 (Management Mechanism) The State Drug Administration (hereinafter referred to as the NMPA) is responsible for the protection of drug trial data (hereinafter referred to as data protection) and is responsible for establishing a data protection system and implementing management work in accordance with the principles of fairness, openness and impartiality.

The Drug Technical Review Center of the National Drug Administration (hereinafter referred to as the Drug Review Center) is responsible for the specific implementation of data protection.

Article 3 (Definition of Concepts) Data protection means that when drugs containing new chemical ingredients and other qualified drugs (see the attached table for details) are approved for marketing,

the National Medical Products Administration shall protect the test data and other data submitted by the applicant that are obtained independently and not disclosed, and grant a data protection period of no more than 6 years.

During the data protection period, if other applicants apply for drug marketing authorization or supplementary application relying on the data in the preceding paragraph without the consent of the drug marketing authorization holder (hereinafter referred to as the holder), the National Medical Products Administration will not grant permission; unless other applicants obtain the data on their own.

During the data protection period, if other applicants submit drug registration applications using data obtained by themselves, their applications shall be approved if they meet the requirements and no longer be granted the data protection period, but the data shall not be relied upon by other subsequent applicants .

Article 4 (Conditions of protected data) Undisclosed trial data and other data refer to trial data in the complete application materials that are not disclosed in the application for drug marketing authorization for the first time in the country.

After a drug is approved, test data obtained when subsequent research work is completed in accordance with the requirements of the drug regulatory authorities will no longer be given new data protection.

Article 5 (Data Protection Related to Innovative Drugs) A six-year data protection period is granted for innovative drugs from the date of their first domestic marketing authorization.

If an original research drug that has been marketed overseas but not in China applies for marketing in China, the data protection period is 6 years minus the time difference between the date on which the drug’s marketing authorization application in China is accepted and the date on which the drug first obtains marketing authorization overseas. The data protection period is calculated from the date on which the drug obtains marketing authorization in China.

The scope of drug data protection in this clause includes all test data used in the drug marketing authorization application materials to prove the safety, efficacy and quality controllability of the drug.

For innovative drugs that have been approved for multiple indications but have the same approval number, each indication will be given data protection according to the registration category, and the scope of data protection for newly added indications will be the clinical trial data that support its marketing.

During the data protection period, the National Medical Products Administration will not approve the marketing application or supplementary application for improved new drugs, chemical generic drugs and biosimilar drugs submitted by other applicants without the consent of the holder, relying on the protected data of the holder , unless other applicants submit data obtained by themselves.

Article 6 (Protection of data related to improved new drugs) A three-year data protection period will be granted from the date of the first domestic marketing authorization for the improved new drug.

If a modified drug that has been marketed overseas but not in China applies for marketing in China, the data protection period is 3 years minus the time difference between the date on which the drug’s

application for marketing authorization in China is accepted and the date on which the drug first obtains marketing authorization overseas. The data protection period is calculated from the date on which the drug obtains marketing authorization in China.

The scope of drug data protection in this clause includes new clinical trial data that demonstrates that the drug has significant clinical advantages over drugs with known active ingredients (marketed biological products), but does not include bioavailability, bioequivalence and immunogenicity data of vaccines.

During the data protection period, the National Medical Products Administration will not approve the marketing application or supplementary application for chemical generic drugs and biosimilar drugs submitted by other applicants without the holder's consent and relying on the protected data of the holder , unless other applicants submit data obtained by themselves.

Article 7 (Data Protection Related to Generic Drugs) A three-year data protection period is granted to the first approved generic drugs (including drugs produced overseas) and biological products of original research drugs that have been marketed overseas but not in China. The data protection period is calculated from the date on which the generic drug or biological product obtains marketing authorization.

The scope of data protection for drugs in this clause includes necessary clinical trial data to support approval, but does not include bioavailability, bioequivalence and immunogenicity data of vaccines.

During the data protection period, the National Medical Products Administration will not approve the marketing application or supplementary application for chemical generic drugs and biosimilar drugs submitted by other applicants without the holder's consent and relying on the protected data of the holder , unless other applicants submit data obtained by themselves.

Article 8 (Application and supporting documents) If the applicant intends to apply for data protection, he/she shall submit an application for data protection at the same time as submitting the application for drug marketing authorization. If there are any questions about data protection-related issues, he/she may apply for communication.

Article 9 (Technical Review) When conducting technical review of drug registration applications, the Center for Drug Evaluation shall confirm the scope and duration of data protection in accordance with the provisions of these Measures.

Article 10 (Granting of Protection Period and Publicity) For drugs that meet the data protection conditions, the National Medical Products Administration will mark the drug's data protection information in the drug approval certificate.

The Center for Drug Evaluation has established a data protection column on its website to publish relevant information on drug data protection.

Article 11 (Acceptance, Review and Approval) After a drug obtains data protection, other applicants can submit drug marketing applications and supplementary applications that rely on the protected data within one year before the expiration of the data protection period . The Drug Evaluation Center will suspend the review time after completing the technical review, and the relevant drugs will be approved for marketing after the data protection period expires.

an applicant claims that the data was obtained independently when submitting a drug marketing application and a supplementary application , but it is discovered during the technical review process that the application relies on protected data of other applicants, the application will not be approved.

Article 12 (Termination of Data Protection) Data protection shall terminate if the drug approval document is revoked, suspended, or cancelled, if the holder voluntarily waives data protection, or in other circumstances prescribed by laws and regulations.

If data protection is terminated, the National Medical Products Administration will issue a notice on the termination of data protection, and the Drug Evaluation Center will update the relevant information in the data protection column based on the notice. From the date on which the National Medical Products Administration issues the notice on the termination of data protection, it can accept or approve drug registration applications submitted by other applicants that rely on the protected data.

Article 13 (Incompliance with data protection information) If, during the review process, it is found that the documents proving the first overseas marketing authorization for drugs submitted by the applicant in accordance with Articles 5 and 6 of these Measures do not match the actual situation , data protection will not be granted; if data protection has already been granted, the data protection will be cancelled.

Article 14 (Data Protection Procedure) The specific working procedures for data protection will be separately formulated by the Drug Evaluation Center.

Article 15 (Effective Date) This regulation shall come into force from now on.

Schedule 1

Chemical Drug Registration Classification and Data Protection Period

Classification	**content**	**Data protection period**
Category 1	Innovative drugs that have not been launched in the domestic or overseas markets.	6 years
Category 2	Improved new drugs that have not been marketed domestically or abroad.	3 years
Category 3	Domestic applicants copy original drugs that are marketed overseas but not in China.	3 years
Category 4	Domestic applicants copy original drugs that have been marketed domestically.	none
Category 5	Drugs that have been marketed overseas can apply for domestic marketing approval.	
5.1	Original research drugs that have been marketed overseas apply for domestic marketing.	6 years – (domestic acceptance time – overseas listing time)
Improved drugs that have been	3 years – (domestic acceptance	

marketed overseas may apply for domestic marketing approval.	time – overseas listing time)	
5.2	Generic drugs that have been marketed overseas apply for domestic marketing.	3 years

Schedule 2

Registration classification and data protection period for preventive biological products

Classification	**content**	**Data protection period**
Category 1	Innovative vaccines	6 years
Category 2	Improved vaccines	3 years
Category 3	3.1 Application for listing of vaccines produced overseas and marketed overseas but not marketed domestically	6 years – (domestic acceptance time – overseas listing time)
	3.2 Vaccines that have been marketed overseas but not in China can be produced and marketed in China	3 years
	3.3 Vaccines already on the market in China	none

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