

Implementation Measures for Drug Trial Data Protection

China – NMPA National Medical Products Administration

Main information

Scope of Application:

Regulating Data Protection of Chemical, Vaccines and Biological Products for the purposes of encouraging pharmaceutical innovation and meeting public demand for medicines.

Effective Date:

May 15th, 2026

Related Provisions:

- Drug Administration Law
- Regulation on the Implementation of the Drug Administration Law
- Announcement of the General Administration on the Release of the Work Plan for the Reform of Chemical Drug Registration Classification (2016 No. 51)

Key Topics

Framework

- **Definition of Protected Data:** Protected data consists of "undisclosed test data and other data" that are submitted by the applicant, self-obtained, not publicly disclosed, and complete, which are used for the first time in a domestic drug marketing authorization application.
- The Regulation relies on the Drug Registration Classification issued in 2016 to set specific data protection periods according to each category. Drugs already marketed in China do not have any protection. Transitory period of 15 days from the Effective date to apply for data protection on pending dossiers.

What's new

- **Fixed Protection Periods by Classification:** The Measures provide clear, tiered data protection periods: 6 years for innovative drugs and certain overseas-originator drugs, 4 years for improved new drugs, and 3 years for the first approved generic of an overseas-originator drug not yet on the domestic market.
- **Delayed Approval Mechanism:** During the data protection period, any other applicant who relies on the protected data to file a generic or biosimilar application will not be approved by the NMPA without the holder's consent, unless the applicant submits self-obtained data that does not rely on the protected data.

Sensitive Factors

- **Public Health and Interest Exception:** In the event of a national public health emergency or when required by public interest, the data protection rules may be overridden according to relevant provisions, allowing other approvals even during the protection period.
- **Conditional approval:** no differences compared with ordinary approval. Where the data protection is granted under conditional approval, post-marketing data do not enjoy new data protection term because they do not constitute new data demonstrating clinical safety and efficacy.

Drivers

- **Time of application:** the applicant shall file an application for data protection at the time of filing its drug marketing authorization application; if the applicant has any questions relating to data protection, the applicant may request communication and exchange.
- **Protection for Localization of Manufacturing:** Overseas companies transferring manufacturing of reference listed drugs to domestic sites can preserve the existing data protection term for the domestically manufactured version, provided the domestic holder obtains the overseas holder's consent. This incentivizes localization while maintaining market exclusivity.



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