Further Optimizing the Review and Approval of Clinically Urgently Needed Overseas Marketed Drugs

China – NMPA National Medical Products Administration

Main information

Scope of Application:

Accelerate the marketing authorization in China of overseas-approved drugs that are urgently needed for clinical use and to meet patients' urgent clinical medication needs

Effective Date:

January 5th, 2026

Related Provisions:

- Announcement on Matters Relating to the Review and Approval of Overseas New Drugs Urgently Needed for Clinical Use" (No. 79 of 2018)
- Specification for Drug Registration and Inspection Work Procedures and Technical Requirements (2025 Revised Edition)

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Key Topics

Framework

- The Announcement concerned integrates and strengthens the provisions of the "Announcement on Matters Relating to the Review and Approval of Overseas New Drugs Urgently Needed for Clinical Use" (No. 79 of 2018), by further allowing drugs that are not included in the previous list under the 2018 Announcement (3 batches of varieties), to apply for the registration (conditional approval), and if the conditions are met, they can be included in the scope of priority review and approval.

What's new

- The Announcement now allows any applicant to request priority status for eligible overseas marketed drugs (including generics and drugs for chronic diseases) on a **rolling, case-by-case basis**, eliminating the need for a fixed list.

- The Announcement adheres to a clinical value–oriented approach and encourages applicants to conduct global synchronized research and development and **submit marketing authorization applications simultaneously in China.**

- **Testing quantity**. The quantity of samples required for registration testing shall correspond to one batch produced at commercial scale, with each batch providing twice the amount needed for quality standard testing. For rare disease drugs with extremely low single-batch yields, applicants may collaborate with the testing institution to determine the minimum sample quantity necessary for registration testing

Sensitive Factors

- It is mandatory the completion of a **Type I communication meeting** and reaching consensus on the evidence package.

- Registration verification and **post-marketing overseas inspections is risk-based**: the method of inspection, whether on-site or remote, shall be determined based on the level of risk.

Drivers

- **Cost Reduction via Evidence Optimization:** The explicit allowance to use existing overseas clinical data and waive local trials for certain generics significantly lowers localization costs.
- **Post-marketing surveillance to leverage the accelerated approval**: supporting materials shall demonstrate the urgent clinical need, including research data supporting overseas marketing authorization, post-marketing clinical use and safety monitoring reports from overseas markets, benefit-risk assessment analyses for cross-ethnic or cross-regional use, and risk control plans following import and marketing in China.