Announcement on Matters Concerning the Application of the Priority Review and Approval Procedures for Drug Marketing Authorization of Chemical Active Pharmaceutical Ingredients

China – NMPA National Medical Product Administration

Main information

Scope of Application:

Eligibility criteria for Chemical Active Pharmaceutical Ingredient (API) to apply for priority review and approval procedures

Effective Date:

August 1st, 2026

Related Provisions:

- Drug Registration Regulations
- Procedures for Priority Review and Approval of Drug Marketing Authorizations (Trial)

Key Topics

Framework

- **Four Eligibility Categories**: API marketing authorization applications qualify if they meet any of the following conditions: (1) the API is associated with a drug product already in the priority review program; (2) it is the first domestic application for an API that has only overseas production sources for a China-approved drug product; (3) it is an overseas API used in an approved originator product, applying for import or domestic production transfer; or (4) it is a drug variety identified as being in market shortage by relevant State Council

What's new

- Formal Expansion of Priority Review to APIs: The Announcement for the first time explicitly outlines the specific categories under which APIs can independently access the priority review and approval pathway, addressing a previous gap in the regulatory framework.
- Streamlined Application for Certain Domestic Substitutes: For APIs in categories (2) and (3), applicants can apply for priority review directly without the need for a prior "communication and consultation" meeting, provided they meet the criteria. This simplifies the application process **for API manufacturers looking to replace overseas supply sources**.

Sensitive Factors

- Strict Eligibility Criteria for Domestic Substitution: The eligibility for domestic substitute APIs (Category 2) is highly restrictive. It applies only to the first domestic manufacturer to apply for an API that has exclusively overseas production sources. This creates a significant "first-mover" advantage and a clear barrier for subsequent applicants for the same API.
- Automatic Eligibility for Certain Products: APIs associated with drug products already in the priority review program are automatically eligible.

Drivers

- **Strict Eligibility Criteria for Domestic Substitution**: The eligibility for domestic substitute APIs (Category 2) is highly restrictive. It applies only to the **first domestic manufacturer** to apply for an API that has exclusively **overseas production** sources. This creates a significant "first-mover" advantage and a clear barrier for subsequent applicants for the same API.
- **Targeting "Market Shortage"** APIs: Identifying APIs that may be considered "market shortage" by the State Council can let Companies supply these high-demand APIs to make the API eligible for direct priority review and, by extension, faster market access.