

Procedures for the Review and Approval of Applications for Conditional Marketing Authorization of Pharmaceutical Products

China – NMPA National Medical Product Administration

Main information

Scope of Application:

Review the 2020 trial version of the Procedures for Conditional Marketing Authorization

Effective Date:

April 22nd, 2026

Related Provisions:

- Drug Administration Law
- Traditional Chinese Medicine Law
- Vaccines Administration Law

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Key Topics

Framework

- The Procedures **apply to drugs meeting the conditional approval criteria** set forth in the Drug Registration Regulations, the Technical Guiding Principles for Conditional Approval (Trial), and the Special Provisions on TCM Registration.
- **Five-step application pathway:** (1) early communication, (2) pre-submission communication, (3) formal application submission, (4) review and approval, and (5) post-marketing confirmatory studies, followed by conversion to regular

What's new

- **TCM Inclusion:** The revised Procedures formally integrate Traditional Chinese Medicine into the conditional approval framework, referencing the *Special Provisions on TCM Registration* and the *Technical Guiding Principles for Conditional Approval*, allowing TCM applicants to apply based on human experience research during the R&D phase.
- **Certificate Validity Rules:** Each conditionally approved indication receives a separate drug registration certificate validity period. The validity period is set to the confirmatory study completion timeline plus one year. The completion timeline is determined through CDE consultation and shall not exceed 4 years from the conditional approval date.

Sensitive Factors

- **Reference Listed Drug Restriction:** Conditionally approved drugs are not designated as reference listed drugs until they convert to regular approval. Generic drug applicants cannot file ANDAs until regular approval and RLD designation, unless they can independently conduct confirmatory studies without relying on the originator's data.
- Holders must submit **annual confirmatory study progress reports** together with the **Periodic Benefit-Risk Evaluation Report (PBRER)** starting from the date of conditional approval.

Drivers

- **Early CDE Communication** for Strategic Planning: The Procedures explicitly encourage early and pre-submission communication meetings (Type II meetings) to align on clinical trial design, efficacy endpoint selection, confirmatory study planning, and priority review eligibility
- **Conversion and Submission Timing:** The Procedures establish a clear conversion pathway—submitting a supplemental application for "conversion to regular approval" or a new indication application with a conversion declaration. Applicants should plan their conversion submissions to align with the certificate validity period (study completion + 1 year) to avoid potential certificate cancellation or indication deletion.



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