Import of Commercial-scale Batches of Drugs already marketed abroad, and produced prior to approval in China

China – NMPA National Medical Products Administration

Main information

Scope of Application:

New provisions on import in China of the Commercial-scale batches of Drugs marketed abroad prior to approval in China – requirements and procedures

Effective Date:

September 29th, 2025

Related Provisions:

- Measures for Administration of Imported Drugs
- Measures for Administration of post-marketing changes of Drugs (trial)
- Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Supervision and Promoting the High-Quality Development of the Pharmaceutical Industry (Guobanfa [2024] No. 53)

Pharm.east.

Key Topics

Framework

- According to the Opinion of State Council no. 53/2024, Imported drugs that have been marketed overseas may be allowed for import and sale in China after obtaining the drug approval certificate, provided that the pre-approval commercial scale batches meet the requirements.
- **Pre-market GMP inspection** is prerequisite for import of commercial-scale batches

What's new

- The "Announcement" connects with relevant laws and regulations, combines clinical needs and industry conditions, and refines relevant matters such as applicable drug categories and conditions to be met to apply and obtain the import permit for commercial-scale batches
- Six eligible categories:
  - original or improved drugs;
  - drug listed in special catalogues of urgently needed drugs (i.e., "Clinically essential drugs subject to shortage", "encouraged generic drugs", etc)
  - drugs whose indications are included in "Catalogue of rare diseases"
  - drugs temporarily imported prior to approval in China
  - drugs approved with accelerate MAH procedures
  - other specified by regulatory authorities
- The announcement is also **applicable to commercial-scale batches in post-marketing changes**, for drugs already being sold in China

Sensitive Factors

- **Full compliance with Chinese standards and GMP is still required**
- **A batch release must be signed after the approval for marketing in China**

Drivers

- **Risk management:** to be handled jointly by the foreign MAH and the designated Domestic Responsible Person
- **List monitoring:** several eligible categories are included in Lists of drugs urgently needed, updated by regulatory authorities
- **Authentication streamlining:** documents certifying that the drug is "authorized for marketing" and the "documentation certifying compliance with drug GMP, where the documents are consistent with those submitted during the drug registration application in China (including supplemental applications or filings) or conform to the format recommended by the World Health Organization, they may be stamped with the domestic responsible party's official seal and **do not require notarization or authentication**.