Guiding Opinions on the Standardized Development of Modern Pharmaceutical Logistics

China – NMPA National Medical Products Administration

Main information

Scope of Application:

The Opinions apply to pharmaceutical wholesale enterprises and third-party logistics (3PL) providers engaged in pharmaceutical storage and distribution within China

Effective Date:

March 20th, 2026

Related Provisions:

- Measures for the Administration of Pharmaceutical Distribution and Use
- GSP Good Supply Practice
- Requirements for Pharmaceutical Record and Data Management (Trial)

Pharm.east.

Key Topics

Framework

- The Guiding Opinions set forth basic requirements regarding pharmaceutical modern logistics facilities and equipment for applicants seeking to establish pharmaceutical wholesale enterprises and for third-party pharmaceutical logistics enterprises engaged in commissioned storage and transportation of pharmaceuticals.

- The Opinions serve as a **technical document** to (a) guide enterprises applying to establish wholesale businesses or 3PL services in meeting basic modern logistics standards, and (b) provide provincial authorities with **guidance for license issuance**, renewal, and routine inspections.

What's new

- Specific requirements applicable **at national level** for 3PL enterprises, including personnel allocation (minimum 2 logistics and 2 IT managers), larger warehouse capacity, dedicated information exchange platforms, and strict contractual obligations with clients.

- **Enterprise information systems** must include at least six core components (ERP, WMS, WCS, TMS, Temperature Monitoring, and Traceability System) that achieve real-time, accurate data exchange with each other.

- A **new requirement for 3PL enterprises** is the configuration of an information exchange platform that supports data exchange with clients, ensuring data records for different clients are mutually non-interfering and not confused.

Sensitive Factors

- Warehouses shall be **self-operated warehouses**. Under Chinese pharmaceutical GSP (Good Supply Practice) regulatory logic, the term "self-operated warehouse" focuses on who actually runs the warehouse operations and bears the legal responsibility, not on who holds the property title.

Drivers

- **Risk Assessment:** Marketing authorization holders, pharmaceutical manufacturers, and pharmaceutical distributors entrusting the transportation of pharmaceuticals shall assess the entrusted party's quality assurance capability and risk management capability, enter into entrusted agreements specifying pharmaceutical quality responsibilities, operating procedures, and other relevant matters, and exercise supervision over the entrusted party. Third-party logistics enterprises shall assess their own capacity to undertake entrusted transportation activities, and the number of entrusting parties accepted shall be commensurate with their actual transportation capacity.
- **Data Management:** Data shall be backed up daily and stored and managed through secure and reliable means (including off-site servers, multi-machine hot standby, or cloud storage). The compliance with the cybersecurity, privacy and trade secret protection laws is mandatory.