China Amended Good Supply Practices for Pharmaceuticals

The Chinese Ministry of Health ("MOH") published the long-awaited amendment of Good Supply Practices for Pharmaceuticals (the "Amended GSP") on January 22, 2013, to be effective as of June 1, 2013.

After three rounds of solicitation for public comments since 2009, the Amended GSP has been significantly expanded from 88 Articles to 187 Articles, divided into four chapters (including the general provisions, the wholesale quality management, the retail quality management and miscellaneous). Unlike the current GSP, which only applies to drug distributors, the Amended GSP will also apply to drug manufacturers selling pharmaceuticals and other activities concerning storage and transportation during the course of drug distribution. Separate GSPs applicable to hospital pharmacies, health stations for birth control and planning and internet pharmacies are yet to be developed by the Chinese State Food and Drug Administration.

The Amended GSP aims to improve drug quality and safety by raising various standards.

- Drug wholesalers and retailers must establish a quality management system, which includes dedicated and qualified quality management personnel and a comprehensive set of quality management documents to govern the operation of quality management function, administration of suppliers, administration of commercial and logistical flows of products, administration of quality incidents, as well as management of facilities and documents.
- Drug wholesalers and retailers are expected to deploy an IT system in order to monitor the entire course of operation and ensure product traceability. The Amended GSP sets forth specific infrastructure requirements for the IT system and requires full implementation of electronic barcoding on incoming and outgoing products.
- The Amended GSP provides more details on warehousing conditions and requirements for storage and transportation of drugs which require cold storage and cold-chain transportation, e.g., requirements on temperature control and monitoring during transportation as well as quality inspection for acceptance. If any third party is engaged for transportation services, drug distributors must specify details of transportation requirements and expected delivery deadlines in an agreement to avoid any compromise on product quality.

The Amended GSP also tightens control on the commercial and logistical flows of products. All sales and purchases of drugs have to be supported by consistent accounting records and official invoices (also known as FA PIAO in Chinese) throughout the entire commercial flow. In addition, products must be accompanied by matching records throughout the entire logistical flow and such records must be verified upon acceptance.

Drug distributors will have a three-year grace period to comply with the Amended GSP. Failure to comply at the end of the grace period will result in suspension or revocation of their pharmaceutical distribution permits.

The implementation of the Amended GSP is likely to accelerate industry consolidation and eliminate poor performers. It will also significantly raise the bar for newly incorporated pharmaceutical distributors. Multinational pharmaceutical companies are advised to carefully examine their existing distribution operations for full compliance with the Amended GSP.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.