China Solicits Comments on Good Supply Practices for Medical Devices

The China Food and Drug Administration (the "CFDA") recently published a draft regulation, *Good Supply Practices for Medical Devices* (the "Draft GSP"), for public comment through January 20, 2014. The first-ever regulation issued by the CFDA on minimum standards for device distribution, the Draft GSP sets forth requirements for procurement, delivery acceptance, storage, sales, transportation, and after-sales services.

The Draft GSP applies to all Class 1, 2 and 3 medical device distributors, as well as third party logistics service providers for medical devices. Notably, the CFDA plans to issue separate rules to regulate good supply practices of online medical device distribution. With reference to ISO13485:2003 and ISO9001, the Draft GSP aims to safeguard the quality and safety of medical devices throughout the entire distribution process, with specific measures on the following areas:

- Quality management system
- Qualification and training for personnel
- Warehousing conditions
- Cold storage and cold-chain transportation requirements
- Exhibition of the medical devices for retail
- Computer information management system
- Management of suppliers
- Comprehensive record management system
- Procurement, delivery acceptance, sale, delivery and transportation, and
- After-sales services.

The Draft GSP does not impose any minimum space requirement for offices and warehouses of device distributors, as the space requirement varies by province. In addition, medical device distributors that only engage in the retail business, distribute medical device software or large medical equipment, or outsource the storage of products to third party logistics service providers, will not need to have a separate warehouse.

Under the Draft GSP, Class 3 medical device wholesalers and retailers shall maintain the delivery acceptance records and sales records for a period of no less than two years after the expiration date of the medical devices. The record retention term for implants is perpetual. In addition, wholesalers of Class 3 medical devices must establish an IT system to retain records of product batch numbers or serial numbers in order to enable traceability.

In anticipation of the promulgation of the GSP, medical device distributors are advised to review their current practices and upgrade the management system to the extent necessary.

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