China Publishes Revised Good Supply Practice (GSP) Standards for Pharmaceutical Products

After several years of drafting and three rounds of public consultation, the Ministry of Health has at last published the revised Good Supply Practice for Pharmaceutical Products (Revised GSP Standards) (药品经营质量管理规范) on 22 January 2013. The Revised GSP Standards will come into effect as of 1 June 2013 to replace the previous version issued in 2000[1].

Key features of the Revised GSP Standards

Higher requirements on quality control and inventory management

Pharmaceutical distributors are now required to establish a comprehensive quality control system, dedicate a specialized department or professional personnel to handle quality control matters, and implement policies regarding quality control. The quality control manager must satisfy certain educational and professional requirements and be a key member of the pharmaceutical distributor's management team.

The Revised GSP Standards also require that the management of inventory be computerized. The distributor must be equipped with the requisite computer and network devices, and maintain an electronic database and other software applications.

Cold chain and humidity control are required for drug storage and must be available in facilities that store, and vehicles that transport, pharmaceuticals.

Key issues

- Key features of the Revised GSP Standards
- Expected interim developments
- Consolidation of China's pharmaceutical distribution sector

Stricter record-keeping and tracking requirements

Distributors are required to maintain suitable documentation at every step of the distribution chain. The products, the accompanying documentation and the distributor's records must be consistent with one another.

As the State Food and Drug Administration (SFDA) is in the process of implementing a tracking system capable of tracing each individual drug SKU (in Chinese 药品电子监管系统), distributors will be required to put in place a system that is

[1]Clifford Chance has commented on an earlier draft version of the Revised GSP Standards. Please see our client briefing titled Amended Good Supply Practice (GSP) Standards Set to Impact Pharmaceutical Distribution Sector, dated October 2011

compatible with the SFDA's tracking system, and to scan the tracking barcode of every drug SKU it distributes into the system.

Expected interim developments

A three-year transition period expiring on 1 June 2016 has been set for the implementation of the Revised GSP Standards meaning that all pharmaceutical distributors must comply with the Revised GSP Standards by this date. The SFDA will only renew existing GSP accreditation and PRC pharmaceutical distribution licenses which expire prior to 1 June 2016 if the requirements of the Revised GSP Standards are met.

According to the Drug Administration Law and relevant regulations issued by the SFDA, a newly- established pharmaceutical wholesaler or retailer must, within thirty days from the date it obtains the PRC pharmaceutical distribution license, apply to the SFDA for GSP accreditation. The SFDA will inspect the facilities of the applicant, and if found to be compliant, the SFDA will issue a GSP accreditation certificate to it which is valid for a term of five years.

Consolidation of China's pharmaceutical distribution sector

The SFDA has been explicit that one of the objectives of the Revised GSP Standards is to accelerate the consolidation of China's pharmaceutical distribution sector. This has long been China's plan, as outlined in China's 12th Five Year Plan and the plan of the Ministry of Commerce in developing the pharmaceutical sector from 2011 to 20152.

Currently there are about 13,000 licensed wholesale distributors in China's pharmaceutical sector. The SFDA projects that a total capital expenditure of seven billion yuan would have to be incurred if the entire industry were to fully comply with the Revised GSP Standards. A large number of smaller distributors with insufficient capital to upgrade their facilities and systems to satisfy the requirements of the Revised GSP Standards are likely to be forced out of the market.

For those multinational pharmaceutical companies which currently hold a PRC pharmaceutical distribution license but outsource their operations to a third party (such as the large state-owned distributor, Sinopharm), the Revised GSP Standards may have little impact as only the third party to which their operations are outsourced needs to hold a GSP accreditation. However, for those pharmaceutical companies with sufficient resources, the impending period of consolidation may present an opportunity to acquire companies which hold a PRC pharmaceutical distribution license and which need funds to upgrade their resources to satisfy the requirements of the Revised GSP Standards.

[2] Clifford Chance has commented on this in our client briefing titled MOFCOM: Consolidating China's Pharmaceutical Distribution Sector dated July 2011

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