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The emergence of cold chain in China

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The Chinese government is promoting the adoption of world-class cold chain standards.

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Both pharmaceutical and biopharmaceutical industries in China have been fast growing in the recent years. A large variety of biopharmaceutical products have been approved and marketed in the country. They are not only gaining increasing acceptance among Chinese patients but also rapidly penetrating more and more therapeutic areas, thus becoming a new but important type of medication.

As most biologic drugs such as recombinant proteins (eg rG-CSF), vaccines and some diagnostic reagents require special care in particular for their storage temperature, the fast development of the Chinese pharmaceutical and biopharmaceutical industries has accordingly raised the standard for management of distribution and delivery of biologic products (the cold chain). How to effectively manage the temperature-sensitive biologic products during each transition stage of the entire cold chain has emerged as an important subject to all Chinese companies that are involved in biologic product manufacturing, sales and distribution. Moreover, it is also a high regulatory priority to Chinese government.

Current situation

At present the effective cold chain management in pharmaceutical product supply chain and logistics service in China is still in its infancy. It was reported that currently about 80 percent of drug products are shipped without appropriate temperature control and record. Some distributors that claim having temperaturecontrolled delivery vehicles/containers actually did not closely monitor the possible fluctuation of temperature during the entire shipping process.

Sometimes, the refrigerator within the delivery vehicle was actually broken but it was not reported to the distribution center immediately. The broken refrigerator thus did not receive immediate repair; nor did the delivery truck have spare refrigeration equipment. The situation did not receive sufficient attention until a number of incidents occurred recently in which vaccines used by

hospitals were found deteriorated. Although it is hard to identify the actual cause, the common sense was set on the delivery process as this is the weakest point in the entire value chain in which currently there is not a system in place in China to specifically regulate and monitor it.

Currently, some provinces or major cities such as Zhejiang, Jiangsu, Shanghai and Beijing have their own local regulations with regards to the control of temperature and humidity for drug product storage and transportation. But there is no united, national standard for the industry. Also, most local standards still lack of the detailed descriptions of how to precisely control, record and report temperature change.

As the Chinese pharmaceutical and biopharmaceutical industry grow, the number of temperature-sensitive drug products is rapidly increasing, including the materials and reagents used in clinical trials (the number of clinical trials conducted in China is also rapidly increasing). But, presently, the effective cold chain management in China is still a brand new concept to many companies, especially those professional logistics service providers. Currently, the main issues reside in the temperature controlling, recording and reporting systems during the entire shipping process and the effective management of these operations. Most incidents are primarily caused by the lack of effective management and regulatory standard to follow.

Most drug companies that manufacture temperature-sensitive drugs such as vaccines have special delivery equipment and vehicles. But many of them usually do not deliver their products to the places far away. They are more willing to sell their drug products in their vicinity areas such as within a delivery radius of about 300 kilometers (or about 188 miles) so that they would have better control over the quality of their products. They generally hand long-distance delivery tasks to those professional carriers. But many of these professional carriers do not have required equipment for temperature-sensitive products. Nor do they have temperature monitoring and reporting systems. To a large extent, the involvement of many such small, third-party distributors attributes to the quality incidents in cold chain management. On the other hand, the frequent deliveries of a small quantity of product packages from drug manufacturers are also the factor that allows these small carriers to enter the market as many large distributors are not interested in delivering the small quantity packages.

At present there are 13,500 drug whole sale companies and 34,000 drug retail sellers or pharmacy stores in China. Another 55,000 or so pharmacy shops are located in the rural areas where industrial infrastructure still falls behind those large cities and the fast transportation is thus difficult. Although it benefits patients in the rural areas to get access to the needed medicines, it raises enormous challenges for drug delivery companies as it is hard to deliver the temperature-sensitive drug products to the rural areas and still ensure their quality.

Furthermore, in many rural pharmacy stores in particular in those remote villages, refrigeration equipment is not always available. In these places, usually, the temperature-sensitive pharmaceutical products such as vaccines are only delivered to the centralized drug stores such as those designated by local county administration. They then deliver the vaccines further to the villages at the time when they are needed. In most cases, vaccines are used right after they arrive, thus avoiding refrigeration. But incidents are still often heard of mainly due to the breach of the operation procedure because of the lack of strict regulation.

The current estimated total market value of the Chinese healthcare supply and logistics service industry is close to RMB 200 billion (US$29.4 billion), growing in about 16 percent a year in the recent years. However, the industry is highly fragmented at present. For example, the combined service revenue of top three companies (SinoPharm, Shanghai Pharma Group and Jiuzhoutong Pharma Group) accounts for only about 20 percent of the market value. As a comparison, in the same industry in the US the top three players account for more than 80 percent of the US market.

The current market value of the Chinese logistics service industry for temperature-sensitive pharmaceutical products is estimated to be US$1.6 billion. Even though the market is still small

(compared with those in the developed countries), the importance of better management for temperature-sensitive pharmaceuticals still cannot be ignored as it is directly related to their final quality.


Major Chinese cities have their own local regulations with regards to the control of temperature and humidity for drug product storage and transportation.

Taking actions

The importance of cold chain management in delivery of temperature-sensitive pharmaceuticals has received government attention. In early 2009 a national policy proposed by six central government agencies was signed into law. It requires that delivery of all pharmaceutical products be handled by qualified professional carriers that possess the required capability and equipment. Later in the same year, the central government also established a special committee responsible for establishing and implementing government polices on nationwide cold chain management. Under the guidance of the committee, the 2010 - 2015 National Development Plans for Pharmaceutical Logistics Service Industry is currently under discussion and expected to be passed soon. In the same regulatory package, National Drug Product Cold Chain Management Standard is also under discussion. In early June 2010, a national conference about establishing national standard for cold chain regulation was held in Hangzhou, the capital city of Zhejiang province. It is expected that the formal national standard will be ready in place and implemented soon.

At present China is also providing a series of trainings to personnel involved in cold chain management. They are organized on a regular basis by both government (such as the SFDA) and private organizations. Some experienced multinational drug companies such as Novo Nordisk and Xi'an Janssen Pharmaceutical (a China subsidiary of Johnson & Johnson) are assisting Chinese government to establish the national standard. China is currently planning to implement the radio-frequency identification (RFID) system for all drug product distributors involved in the cold chain management as the system is able to record temperature at scheduled time points and report the real-time temperature to centralized database. The government is also encouraging third party (professional drug distributors) to take charge of most part of the drug distribution in the country. They are also encouraged to consolidate so as to concentrate resource, increase efficacy and enhance overall capability. It is expected that the industry will be more integrated in the near future with those large, technically more capable providers dominating the market.

Good players

Until now, drug companies in China are still the primary party responsible for delivering temperature-sensitive drug products. Professional carriers that possess the required temperaturecontrolled transportation capability are still rare.

Although it is still nascent, a number of new players in this Chinese industry have emerged. They are following the international standard and have installed the integrated temperature recording system (such as RFID) for all containers they use to ship temperature-sensitive pharmaceutical products. These companies also provide constant trainings to their personnel involved in the delivery process and emphasize their accountability for service quality. Table 1 listed some representative service providers in this Chinese industry.

Company	Capability
Jiuzhoutong Group (Beijing)	Recently built a large drug distribution center in Shanghai and installed RFID system in all its delivery vehicles that deliver temperature-sensitive drug products.
Huadong Medicine Group (Zhejiang)	Recently installed RFID system in its delivery vehicles. Its Ningbo logistics service center consists of more than 300 well trained professionals.
Hainan Tailin Biological Products (a subsidiary of Tailin Pharma Group)	In its delivery vehicles, all containers have had RFID system since 2003.

Table 1: Representative Chinese companies involved in cold chain management

Zhejiang International Logistics Service, a drug delivery specialist based in Zhejiang province (also a subsidiary of Zhejiang Int Medicine), was the pioneer company that took initiatives in 2007 to set company quality and operation standard for delivery of temperature-sensitive pharmaceuticals. Shortly after that (in 2008), based on the company standard of International Logistics Service, the regulatory body of Zhejiang province launched its first provincial standard and required all companies in the province involved in the pharmaceutical product delivery to follow the standard. As the cold chain management for temperature-sensitive pharmaceutical products received official attention, this provincial standard, after numerous revisions, is now being considered to be converted to national standard.

The future

Under the above positive environment, in the recent one year or so, a number of new pharmaceutical logistics service companies emerged in China. Some are financially backed by venture capital investors. For example, Jiangying Medical Fund Management, a local Chinese venture capital investor, invested RMB 150 million (or about US$22 million) in a Fujian-based pharmaceutical logistics service company, Luyan Group. Jiangying also recently invested in LuRengtang Pharma Group (in Hebei province), currently the third largest pharmaceutical logistics service company in China.

Although it is still a long way for China to reach the current standard of cold chain management level in the developed countries, the current timing is perfect for the country to emphasize the importance as the healthcare reform recently initiated by Chinese government calls for reduction of middlemen in pharmaceutical product distribution chain in order to reduce cost and eventually the price of pharmaceuticals.

As a complete regulatory system is being gradually established and the respective laws are being implemented, the overall environment in China's cold chain management industry will be greatly improved. It is thus expected that the Chinese pharmaceutical logistics service industry will be growing in a fast pace in the near future.