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China Life Sciences Health Industry Client Briefing – February 2013 (March 11, 2013)

Pharmaceuticals, Medical Devices, Health Care & Life Sciences News & Regulations

New Drug GSP Issued: Supervision on Drug Distribution to be Enhanced *(China Securities Journal 2013-02-20) – February 20, 2013*

The State Food & Drug Administration (SFDA) issued revised Good Supply Practices of Drugs (New GSP), effective June 1, 2013, to upgrade the current requirements for drug distribution and supply chain management in China. The New GSP consists of 187 articles, spanning four chapters, and adds requirements regarding the following:

- **Information Management:** The New GSP sets forth detailed requirements for computer management facilities, network environments, databases, and application software. To ensure electronic monitoring of drug products, distributors must establish local area networks, information platforms, and computer systems.
- **Cold Chain Management:** Distributors of the raw material for traditional Chinese medicine (TCM) and herbal slices must establish dedicated warehouse and maintenance locations. Drug distributors engaged in the distribution of chilled and frozen products must be equipped with cold storage systems, monitoring and alert equipment, spare power supply, and refrigerated vehicles and incubators.
- **Transportation Management:** A drug distributor must review the qualifications of, and sign liability agreements with, any third party engaged in the transport of its drug products.
- **Sales Records Management:** A drug distributor must keep documentation of the delivery and transport of drug products, including the issuance of invoices for any drug procurement.

The SFDA has set a three-year transition period for drug distributors to comply with the requirements set forth in the New GSP. Drug distributors not in compliance with the revised requirements by the prescribed deadline may be banned from their drug distribution operations in China.

China to Encourage Innovative Drug Development (Xinhua News Agency 2013-02-27) – February 27, 2013 To encourage the innovative research and development of new drugs, the SFDA recently announced a plan to reform the drug examination and registration process for both new and generic drugs. To further streamline the drug approval process for new drugs, the SFDA intends to encourage development by focusing on clinical value and by shortening the approval process for those drugs developed from self-owned intellectual property rights. The SFDA will give priority to some generic drugs during the drug approval process, such as those in short supply or those used to treat rare diseases. The plan also calls for more stringent quality control for clinical trials, including additional protection for clinical trial subjects. Finally, the SFDA intends to encourage the research and development of drugs used by children.

Baidu, SFDA, Team Up on Drug Search (Global Times 2013-02-25) – February 26, 2013 In a bid to crack down on false drug information posted on the Internet, Baidu.com, China's largest Internet search engine, has partnered with the SFDA to clean up the data generated through online searches of medicines and online drugstores. Online search results on Baidu will provide detailed information obtained from the SFDA about medicine specifications and licensed drug producers.

TCM Manufacturer Urged to Raise Awareness of Drug Side Effects (Xinhua News Agency 2013-02-07) – February 7, 2013 Following a recall of Yunnan Baiyao, a TCM product used to treat open wounds and muscle pain, the SFDA has ordered the manufacturer to raise public awareness of the product's side effects. The Department of Health of the Hong Kong Special Administrative Region recently recalled Yunnan Baiyao after finding that it contains an undeclared amount of aconitum alkaloids, which, if ingested improperly, may cause some side effects.

Favorable Policies Support Biopharmaceutical Stocks (China Daily 2013-02-08) – February 16, 2013 According to industry observers, China's encouraging policies for the biological industry are supporting the country's share prices in the biopharmaceutical sector. The 12th Five-Year Development Plan for the Biological Industry, issued by the National Development and Reform Commission – China's top economic planner – indicates that the biological pharmaceutical sector is one of the seven key industries that China will support by 2020.

Medical Firms See Healthy Foreign Trade Growth (*China Daily* 2013-02-06) – February 6, 2013 Statistics recently released by the China Chamber of Commerce for Import & Export of Medicine & Health Products, an organization under the Ministry of Commerce, indicate that the export and import volume of China's medical industry totaled \$80.95 billion in 2012, a record growth of 10.5 percent. The Chamber expects this figure to surge even higher, to 12 percent, for 2013.

China's Medical Device Market to Grow Rapidly (*Xinhua News Agency* 2013-02-05) – February 5, 2013 The increasing demand for the upgrade of outmoded medical devices in Chinese hospitals is expected to spur rapid growth of the medical device market. According to a China Med 2013 press conference – an annual international exhibition for medical devices – 60 percent and 15 percent of the medical devices installed in the country's 175,000 health institutions are dated from the mid-1980s and 1970s, respectively.

Implementing Programs for Serious Illness Health Insurance Issued in Several Provinces (*People's Daily* 2013-02-17) – February 17, 2013 Several provinces, including Qinghai, Shaanxi, Fujian, Zhejiang, Guangxi, Anhui, Shandong, Liaoning and Jilin, have established local programs to assist with the implementation of health insurance policies for serious illnesses. According to the Guiding Opinions Concerning Carrying Out the Serious Illness Health Insurance for Urban and Rural Residents (Opinions), medical insurance participants are entitled to additional reimbursement for expenses incurred from the medical treatment of serious illnesses, as long as the self-paid portion (excluding the basic reimbursement) exceeds the local annual per capita income. The Opinions further require the actual reimbursement rate to be not less than 50 percent of total medical expenses. Following the implementation of the local programs, the actual reimbursement rates in the provinces of Qinghai, Guangxi and Ningxia are expected to reach 80 percent to 90 percent; 53 percent; and 50 percent to 81 percent, respectively. In addition, to provide a wider scope of protection, some provinces intend to combine basic medical insurance with serious illness insurance, and medical aid and commercial insurance.

China Forbids Linking Doctors' Incomes with Patient Medical Expenses (*Xinhua News Agency* 2013-02-20) – February 21, 2013 The Health Reform Office under the State Council, or China's Cabinet, recently released guidelines prohibiting hospitals from linking doctors' incomes with their patients' medicine and medical exam expenses. Because some hospitals link doctors' incomes with the revenue earned through medication sales and exam fees, which results in greater economic burden for patients, the guidelines are intended to consolidate and improve the basic health care system in China through solutions related to local-level health care reform.

Provinces Urged to Buy Insurance (*China Daily* 2013-02-22) – February 22, 2013 The Ministry of Health (MOH) recently announced a public insurance program, the New Rural Cooperative Medical Scheme, to help rural residents cope with the costs of medical treatment for severe chronic diseases. The program, which will be independently operated at the provincial level, will spend about 15 yuan (\$2.38) per person annually to purchase commercial insurance for farmers in rural areas. This latest measure follows the issuance of a statement in August by the National Development and Reform Commission, the MOH, and four other state-level government agencies, requesting provinces to purchase commercial insurance to help alleviate the heavy financial burden associated with treating severe chronic diseases for rural residents who do not have such coverage.