

China Briefing - March 2012 (April 13, 2012)

13 April 2012

Authors: Jay J. Yan, Mao Rong, Amy Yin, Gordon B. Schatz

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

News

- **American Medical Device Maker Accused of Bribery to Doctors in China and other Countries (Xinhua Net 2012-03-27) – March 27, 2012**

On March 26, 2012, the United States Securities and Exchange Commission (“SEC”) accused an American orthopedic device maker of bribery in foreign countries and of violating the Foreign Corrupt Practice Act (“FCPA”). According to SEC allegations, from 2000 to August 2008, the company’s subsidiaries and distributors bribed doctors at public hospitals in Argentina, Brazil and China for the purpose of obtaining or retaining business. In addition to cash bribes, the company was accused of paying illegitimate international travel expenses for Chinese doctors. To settle this charge, the company agreed to pay \$17.28 million in criminal penalty to DOJ and \$5.4 million in disgorgement of profits and pre-judgment interest to SEC. Recently, U.S. regulatory authorities have pushed aggressively for the enforcement of the FCPA. Last year, well-known drug and high-tech companies were accused of violation of the FCPA by the SEC.

- **Qiagen Inks HPV Screening Deal with China's KingMed Diagnostics (GenomeWeb 2012-03-08)**

Qiagen has signed a co-marketing deal in China with KingMed Diagnostics aimed at expanding access to its digene HPV test. KingMed is China's largest independent laboratory network, according to Qiagen, and under the agreement will serve as a centralized lab. This will allow smaller hospitals and those in less-populated areas to offer the HPV test and send samples to KingMed for processing and analysis. Victor Shi, Asia Pacific president of Qiagen, said in a statement that the agreement will bring the test to regions where it is most needed. "Qiagen and KingMed Diagnostics have had a long and fruitful collaboration which we are now significantly expanding," he added.

- **Medical Care Administration to Improve through Health Cards (China Daily 2012-03-02) – March 2, 2012**

The Ministry of Health (MOH) issued the nation's first batch of resident health cards on Thursday to improve the efficiency of medical services and to facilitate fee transactions across regions. As a pilot program, the cards are first being issued to residents in Henan, Liaoning, and Guangdong provinces, and the Inner Mongolia autonomous region. When the program is implemented nationwide, it will link hospitals, public health institutions

and insurance operators across China, Minister of Health Chen Zhu said at a ceremony marking the launch of the pilot program.

The MOH also formulated a Notice to regulate the issuance, production, use and management of resident health cards. The Notice includes six administrative measures and five technical specifications as follows:

- Administrative Measures on Resident Health Card Life Cycle
 - Administrative Measures on Individuals' Resident Health Card
 - Administrative Measures on Encryption Key of Resident Health Card
 - Administrative Measures on Life Cycle of Secure Access Module of Resident Health Card
 - Administrative Measures on Product Testing of Resident Health Card
 - Administrative Measures on Filing of Manufacturing Entities and Products of Resident Health Card
 - Amendment to the Technical Specifications on Resident Health Card
 - Command Set for Resident Health Card (User Card)
 - Application Specifications on Resident Health Card
 - Technical Specifications on Resident Health Card Terminals
 - Product Testing Specifications on Resident Health Card (User Card) and Terminals
- **Cuts in Drug Prices (*China Daily* 2012-03-13)**

Reforms will see drug prices lowered, said reporters from East China cities like Zhenjiang, Shanghai and Huangshan. For decades, Tan Shijin, a rural resident in Anhui province, refused to visit his local community health center for fear of high drug prices. Instead, whenever he was sick, he would travel 5 kilometers to the nearest public hospital. Things have changed in recent years, however, largely thanks to a drug-procurement platform that has standardized the prices of about 600 essential medicines at rural clinics in Anhui and reduced the average cost for patients by more than 40 percent. Reforms of the health sector began nationwide in 2009. However, experts and industry insiders say the process has entered a critical stage, especially for public hospitals.

- **China to Help TCM Extend Global Reach (*China Daily* 2012-03-13) – March 13, 2012**

China plans to open more Confucius Institutes overseas to teach traditional Chinese medicine and to promote the Eastern medical science, Deputy Minister of Health Wang Guoqiang said Monday. "We are working closely with the Ministry of Education and the Confucius Institute headquarters to open more TCM Confucius Institutes and to add TCM-related courses to the syllabus of existing ones," said Wang, who is also director of the State Administration of TCM. "TCM, particularly its preventive aspect, is very well received abroad, regardless of nationality or ideology," Wang told China Daily in an interview Monday.

However, he added, China lacks skilled TCM practitioners who speak a foreign language.

- **Maternity Insurance to Achieve Full Coverage in Beijing: Every Mother Participating in Medical Insurance Will Get Reimbursed (*China Court* 2012-03-20) – March 20, 2012**

Starting from April 1, the self-employed and the unemployed in Beijing may have their maternity expenses reimbursed. According to China's current social insurance policies, maternity insurance contributions are made by a person's employer. Since the self-employed and the unemployed do not have an employer, they are not able to participate in maternity insurance. After April 1, however, so long as these people have participated in the medical insurance scheme, their maternity expenses can be reimbursed out of the medical insurance funds. It is reported that Beijing maternity reimbursement includes maternity surgery fee and maternity allowance. The self-employed and the unemployed can only enjoy the surgery reimbursement, but not the maternity allowance.

- **MOH Encourages Private Capital into Medical Rehabilitation Service (*Beijing Daily* 2012-03-22) – March 23, 2012**

Given the increase in China's aging population and its 83 million disabled and 270 million patients suffering from chronic diseases, China has a huge demand for rehabilitation services. Ma Xiaowei, Vice-Minister of Health, said in a meeting that the MOH will encourage conversion of qualified general hospitals at Class II level into rehabilitation hospitals or into general hospitals with medical rehabilitation as their main service. In the meantime, private capital is encouraged to enter into the medical rehabilitation sector. The MOH promises a fair environment for private rehabilitation institutions in terms of market access and government supervision.

- **China Committed to Reform Organ Transplants within Three to Five Years (*Xinhua News Agency* 2012-03-23) – March 23, 2012**

Vice-Minister of Health said March 22 that China will establish an organ donation system as soon as possible, and that the country will use donated organs to eliminate the reliance on death row prisoners for organ transplants within three to five years. According to statistics of the MOH, around 1.5 million people need organ transplants in China every year. However, only 10,000 undergo transplant surgery every year because of the lack of organs. An after-death organ donation system is being developed and 16 provinces and municipalities have initiated pilot projects. China will also amend its legislations to encourage citizens to donate their organs

after death. Among these, the Rules on Transplant of Human Organs (Amendment) have been put on the 2012 legislative agenda of the State Council. China is making an effort to make organ donations the main source for organ transplant.

- **Health Care Reform Roadmap (*China Daily* 2012-03-26) – March 27, 2012**

Health care reform is meant to provide residents with an affordable, quality medical service, which explains why any central government policy on health care catches the attention of the public. The latest State Council document on health care reform until the end of the 12th Five-Year Plan period (2011-15) proposes an explicit roadmap. What is particularly noteworthy is that health care administrative departments at all levels will be required to tighten control over the rise in medical costs, including the cost of hospitalization and the proportion of drug costs within the total bill for treatment.

- **Publication of Administrative Measures on Scientific Research of the Traditional Chinese Medicine Industry (*China News of Traditional Chinese Medicine* 2012-03-28)**

Recently, the State Administration of Traditional Chinese Medicine issued Interim Measures on the Administration of Scientific Research Projects in the Traditional Chinese Medicine Industry. The Measures provide detailed rules on responsibilities and division of work for the entities that implement and organize scientific research; procedures for project approval; supervision and examination; and performance evaluation, among other things. The projects will focus on basic research on the application of traditional Chinese medicine, pre-research on significant traditional Chinese medicine techniques (methods, programs), R&D on practical techniques, research on national standard and major industrial technical standards, research on traditional Chinese medicine measurement, and research on inspection and detection technologies.

Regulations

- **Notice Concerning Registration after Adjustment of Classification of Medical Devices — March 5, 2012**

If a medical device was originally registered under a higher-level classification and is now subject to a lower-level classification, the registration certificates will continue to be valid. Upon expiration of the certificates, the medical device will be registered under the new classification. If the medical device was originally registered under a lower-level classification and is now subject to a higher-level classification, the medical device manufacturer should apply for re-registration pursuant to Article 35 of the Administrative Measures on Registration of Medical Devices. The original certificate continues to be valid until the re-registration is completed. For those medical devices no longer subject to any classification, the original certificates will cease to be used.

- **Wholly Owned Hospitals Established by Hong Kong and Macau Service Providers Permitted in All Major Chinese Cities – March 30, 2012**

According to China's MOH, as of April 1, Hong Kong and Macau service providers may set up wholly owned hospitals in Beijing, Shanghai, Tianjin, Chongqing, and capitals of all provinces and autonomous regions in the mainland. The MOH said that this was in line with Supplement VIII of the Closer Economic Partnership Arrangement with Hong Kong and Macau, respectively. Currently, only Shanghai, Chongqing, Guangdong, Fujian and Hainan permit the establishment of such hospitals.

If you have questions or would like additional information on the material covered in this Alert, please contact one of the contributors or the Reed Smith lawyer with whom you regularly work.

About Reed Smith

Reed Smith is a global relationship law firm with more than 1,600 lawyers in 23 offices throughout the United States, Europe, Asia and the Middle East.

The information contained herein is intended to be a general guide only and not to be comprehensive, nor to provide legal advice. You should not rely on the information contained herein as if it were legal or other professional advice.

Reed Smith LLP is a limited liability partnership registered in England and Wales with registered number OC303620 and its registered office at The Broadgate Tower, 20 Primrose Street, London EC2A 2RS. Reed Smith LLP is regulated by the Solicitors Regulation Authority. Any reference to the term 'partner' in connection to Reed Smith LLP is a reference to a member of it or an employee of equivalent status.

This Client Alert was compiled up to and including April 2012.

The business carried on from offices in the United States and Germany is carried on by Reed Smith LLP of Delaware, USA; from the other offices is carried on by Reed Smith LLP of England; but in Hong Kong, the business is carried on by Reed Smith Richards Butler. A list of all Partners and employed attorneys as well as their court admissions can be inspected at the website <http://www.reedsmith.com/>.

© Reed Smith LLP 2012. All rights reserved.