China Life Sciences and Health Industry Client Briefing – July 2012 (August 8, 2012)

8 August 2012

Authors: Jay J. Yan , Hugh T. Scogin , Jr. , John Tan , Katherine Yang , May Ling Wong , Gordon B. Schatz

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

News

 Counterfeit Drug Crackdown in China (Xinhua News Agency 2012-08-05) – August 5, 2012

According to China's official news agency, Xinhua, nearly 2,000 people have been arrested or detained for alleged sale or distribution of counterfeit drugs and healthcare products. As part of this major enforcement effort, Chinese officials had seized over \$180 million in counterfeit drugs for the treatment of cancer, hypertension, and diabetes. Some of the practices of particular concern appear to be hospital workers who save old drug packages and re-sell the packages to counterfeiters who put fake drugs in the packages. Some fraudulent medicines are being marketed over the internet, direct to consumers, and these can be more difficult for the government to monitor. The government has stepped up enforcement of food and drug products that pose a health and safety risk. It appears some of the fake drugs subject to this most recent enforcement can cause liver damage or cardiac arrest. China's Ministry of Public Security said it would offer rewards to individuals who help to uncover counterfeit drug activities. This suggests that China, like other countries, is looking to leverage citizen whistle blowing, as part of the enforcement process. It may also be that such issues become more prominent with the upcoming changes in China's national political leadership.

 China Agencies Drafting Policies to Accelerate Development of Medical Devices, Supporting Fund to be Introduced in July (Shanghai Securities News 2012-07-05) – July 5, 2012

The medical device industry constitutes a major part of China's strategic growth industries. China currently has 14,000 medical device manufacturers and more than 40,000 medical device distributors. From January to May, medical device production reached RMB 55.69 billion, a year-on-year increase of 20.6 percent. However, China sales of medical devices account for less than 3 percent of the total global medical device market. In order to further accelerate developments of China's medical device industry, the Ministry of Industry and Information Technology, the National Development and Reform Commission and the Ministry of Science and Technology are working on new supportive policies and measures, which are expected to be issued later this year. Additionally, the Ministry of Health and other government agencies (NCRC, MIIT, MOF) announced a specialized fund of RMB 1.5 billion, which will be used to support the development of key medical device technologies. This fund was expected to launch in July, but has not yet become operational.

Mindray Medical Completes Acquisition of Dragonbio's Orthopedics Business (www.beckersasc.com 2012-07-19) – July 23, 2012

Mindray Medical International Limited (NYSE: MR), a Chinese medical device manufacturer focusing on patient monitoring products, in vitro diagnostic products and medical imaging systems, recently announced the completion of its acquisition of Wuhan Dragonbio Surgical Implant's orthopedics business. The companies had previously reached agreement on the acquisition in June. Mindray reportedly paid \$35.5 million for a controlling stake in Dragonbio.

Multinational Medical Device Companies Focus on Grassroots Market (China Daily 2012-07-26) – July 26, 2012/July 30, 2012

GE Healthcare is targeting its diagnostics products, such as the VScan ultrasound device, at both major urban hospitals and grassroots medical institutions, including village clinics, county and township hospitals and community health clinics. "It's especially useful for general practitioners in rural areas, where big and expensive imaging machines are few and far between and doctors often travel from village to village visiting patients," said Liu

Simin, GE Healthcare China's clinical marketing manager. Such devices are easy to carry, offer high-quality imaging, and enable data transfer to facilitate remote consultations. Rachel Duan, President and CEO of GE Healthcare China, said the company plans to increase its sales in the grassroots market from less than 20 percent of the company's current total to more than 50 percent in the next three to five years, and 70 percent of the company's new products will be tailored to grassroots health care needs. Other major multinational medical device manufacturers, such as Siemens and Philips, are also developing innovative medical products to serve the special needs of China's rural population and China's emerging healthcare infrastructure at the grass-roots level. Providing new products and ensuring that health care personnel know how to use the devices are essential to long term quality care.

• J&J Plans Training Center in China (China Daily 2012-07-12) – July 13, 2012

Johnson & Johnson Medical (China) Ltd said it will soon establish its third medical-care training center in China, targeting Chinese medical practitioners in Shenzhen and Guangzhou. The company said the new center will meet increasing professional-training needs in China and supplement the functions of its current academic and training facilities in Beijing and Shanghai.

New Round of Drug Price Cuts Expected, Maximum Cut to be More Than 20 Percent (Xinhua Net 2012-07-27) – July 27, 2012

Multiple sources indicate that the National Reform and Development Commission will initiate a new round of drug price cuts this year, targeting cancer drugs, blood products, immunomodulating drugs, and other high profit-margin medicines. The sources indicated that price cuts may exceed 20 percent, although blood products in severe shortage may not be affected. Additionally, the 700 price cuts target cancer drugs and blood products with high profit margins. An official from the Ministry of Health disclosed that the National Essential Drug Catalogue may be expanded to cover a total of 700 types of drugs, significantly more than the 500 categories originally anticipated. The MOH official noted that the current essential drug list does not cover blood products that are listed in the World Health Organization list of essential drugs. The expansion of the Essential Drug Catalogue is expected to be targeted at the needs of Tier Two and Three hospitals.

China Pharmaceutical Group Loses Bid to Toss Vitamin C Case (China Daily 2012-07-20) – July 20, 2012

China Pharmaceutical Group Ltd, Weisheng Pharmaceutical Co., Hebei Welcome Pharmaceutical Co., North China Pharmaceutical Group and Northeast Pharmaceutical Group, have lost their bid for dismissal of antitrust claims in a vitamin C price-fixing lawsuit. On July 18, U.S. District Judge Brian M. Cogan (Brooklyn, NY) denied the companies' request to be dismissed from the suit. Trial is now scheduled for November 5 on allegations that the defendants inflated prices for bulk vitamin C.

Drug Firm Wins Herbal Tea Trademark Litigation, Trade Dress Dispute Ongoing (Hengyuan Zhiye 2012-07-17) – July 17, 2012

On July 16, the Beijing First Intermediate Court ruled that Guangzhou Pharmaceutical Company Limited owns the "Wong Lo Kat" herbal tea trademark name, ending a lengthy dispute with Hong Kong's JDB Group. However, the JDB Group has changed its tea's name while keeping the same bright red can. The use of the red can is now the subject of a trade dress dispute between the companies.

MOH Enhances Planning of Private Medical Institutions and Further Relaxes Threshold for Private Investors (China Securities Journal 2012-07-11) – July 11, 2012

The Ministry of Health (MOH) promulgated the Notice Concerning Regional Health Planning and Medical Institutions and Promoting the Development of Private Medical Institutions, which sets a goal for non-public medical institutions to provide 20 percent of total hospital beds and medical services by 2015. Local government will encourage private enterprises, charitable institutions, foundations, commercial insurance companies and overseas investors to establish private medical institutions. Qualified individuals are also encouraged to open private clinics. MOH stated that China will encourage private investors to establish rehabilitation hospitals, nursing homes, geriatric and chronic disease clinics, and other medical institutions. Investors will also be encouraged to focus on weak areas of the medical services industry such as pediatric, mental health, and EMT services. MOH will further encourage private investors to set up independent diagnostic imaging, testing and pathology clinics.

• Foreign Investors Eye Medical Services (China Daily 2012-07-23) – July 23, 2012

The recent opening of the first wholly Taiwanese-funded hospital in Shanghai sent a positive signal regarding overseas investment in medical institutions on the Chinese mainland. Shanghai Landseed International Hospital, which is also the first totally Taiwanese-invested hospital on the mainland, opened on June 26 in Shanghai. It is the first Taiwanese hospital to benefit from the signing of the Economic Cooperation Framework Agreement in 2010, and the first wholly foreign-funded hospital on the mainland. The hospital was built with 150 million yuan (\$24 million) from the Taoyuan-based Landseed International Medical Group, which entered a joint-venture to build Shanghai Chenxin Hospital in 2002. It is also worth noting that a similar treatment is available for investors from Hong Kong and Macao under the Closer Economic Partnership Arrangement to set up wholly owned hospitals in Shanghai, Chongqing, Fujian, Guangdong and Hainan.

MOH: Three Public Health Projects for Women and Children Added in 2012 Medical Reform (E-north 2012-07-17) – July 17, 2012

The Ministry of Health (MOH) announced yesterday that three public health projects for women and children will be added to the 2012 medical reforms. These projects include:

- A pilot nutrition program for children in poor areas, in which China will provide nutritional supplements for children in 100 counties of eight destitute areas across 10 provinces and municipalities
- A thalassemia screening program, in which prenatal screening and prenatal diagnosis will be introduced into Guangxi, Hainan and Yunnan to deal with the high incidence of thalassemia
- Finally, Yunnan and Xinjiang will offer subsidies for neonatal disease screening in order to encourage early diagnosis and treatment of hereditary metabolic diseases

• Li Keqiang Calls for Further Medical Reforms (China Daily 2012-07-20) – July 20, 2012

On July 18, Vice-Premier Li Keqiang urged the country to push forward with medical reform. The basic public health insurance system covers both urban and rural areas, but does not yet cover people with acute and serious chronic diseases, Li said. Li noted that a person who suffers from such an illness is likely to impose a major financial burden on

their entire family. Li urged medical reformers to cover acute and serious chronic diseases under the current public health insurance system. Li also suggested that the insurance industry and the government cooperate to help individuals combat such diseases and their related costs.

Medical Reforms Should Aim at Preventing Disease (China Daily 2012-07-24) – July 25, 2012

Government officials and experts participating in a forum organized by the Economist magazine agreed that China should focus on improving public health and preventing diseases, even as it is struggling with the ever-increasing cost of medical care. The forum discussed the successes and obstacles China has encountered in its recent attempts to reform its medical care system.

Regulations

• Notice Regarding the Code of Conduct for Medical Personnel – July 19, 2012

The Ministry of Health issued this Notice to regulate the behavior of medical personnel, including hospital management personnel, physicians, nurses, pharmacists, technicians and other staff. Although some portions of the code – such as the prohibition on accepting bribes – repeat the content of other regulations, much of the code is new. Moreover, this is the first time the Ministry of Health has gathered the various regulations on medical personnel's conduct in one place. Some key portions of the code of conduct:

- 1. medical personnel are required to respect patient's right to informed consent and to keep patient information confidential
- 2. medical personnel are prohibited from:
- discriminating against patients based on their race, religion, social class, disability, disease or other reasons
- exaggerating the seriousness of an illness or over-treating an illness
- selling the numbered tickets used to register for medical treatment at hospitals

- committing fraud against the national health insurance program
- accepting kick-backs or commissions offered by producers and distributors of medical devices, pharmaceuticals, and their agents in any form whatsoever, or attending commercial entertainment activities arranged, organized or paid by such producers or distributors, etc.

The Notice applies the code of conduct to all practitioners, and also rural doctors, trainees, and outsourced service staff.

The practitioners who violate the code will be subject to various sanctions, including disqualification and loss of accreditation, dismissal, administrative punishment imposed by health authorities, and even criminal liabilities depending on the seriousness of the case. When conducting annual review and grade assessment on the practitioners by the medical institution, compliance with the code will be viewed as a significant basis for the grading of medical institutions. Implementation of the notice and code will likely be phased in starting with certain medical institutions, and local health authorities will conduct corresponding supervision.

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 July 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.