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China Life Sciences and Health Industry Client Briefing – October 2012 (November 16, 2012)

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

News & Regulations

- **China Becoming Healthcare R&D Hub (*China Daily* 2012-10-09) – October 9, 2012**
Global companies, such as GE and Ipsen, are seeing their businesses expand rapidly in China's market. GE Healthcare has sold 100 of its new optical magnetic resonance machines in China over the past nine months, and 500 across the globe during the past two years. These are strong sales figures, but perhaps more striking is the fact that the machine is both manufactured and developed in China. China contains an important part of the company's international research and development capabilities, and has been integral in its global business model for some years, according to Richard Hausmann, Vice-President of magnetic resonance healthcare systems at GE Healthcare, the medical arm of General Electric Co.
- **Imported Drugs to Go on China's Electronic Monitoring Network (*Xinhua News Agency* 2012-10-08) – October 9, 2012**
China's food and drug safety watchdog plans to put imported drugs on the national electronic monitoring network in a move to step up drug management. Overseas pharmaceutical companies and their designated agents in China will have to apply to be covered by the network and get relevant cipher keys, the State Food and Drug Administration (SFDA) said in a draft regulation. The regulation was made public to solicit opinions until October 12, 2012. The electronic network was designed to monitor the entire process of manufacturing, transportation, storage and the sale of drugs. The move will also enable real-time inquiries into inventories and destinations, according to Wang Yingli, Chief of the SFDA information planning office.

- Guangxi to Build Pharmaceuticals as a Pillar Industry (21st Century Business Herald 2012-10-25) – October 25, 2012** Experts recently reviewed and approved the draft *12th Five-Year Development Plan for the Biopharmaceutical Industry in Guangxi Zhuang Autonomous Region* (for public comment), according to *21st Century Business Herald* October 25. According to the plan, the total output value of Guangxi's biopharmaceutical industry is expected to reach RMB34 billion by 2015, with an average annual growth exceeding 18 percent; industrial value added output is also expected to reach RMB14 billion by 2015, with an average annual growth of more than 20 percent.
- China to Set Up Database for Organ Transplants (China Daily 2012-10-10) – October 10, 2012** A Ministry of Health spokesman said that a national database to record and distribute human organ donations will be established. The ministry has already drafted an organ distribution regulation, spokesman Deng Haihua said, adding that the regulation must pass a trial phase first. A network for organ donations and transplants will be formed by 164 qualified hospitals nationwide.
- Private Medical Care Gets Boost (China Daily 2012-10-08) – October 8, 2012** The details of a policy that aims to encourage private investment in Beijing's medical care sector are expected to be effective by the end of this month. Issued by the Beijing municipal government at the end of August, the details reflect a new and long-anticipated development of the country's medical reform. In early August, Wenzhou, in Zhejiang province, developed new plans to offer incentive policies for investors that could establish the city as the private medical capital of China. Like Beijing and Wenzhou, several other local governments are competing to lure private, including foreign, capital into their health care regimes.
- State Council Issues the 12th FYP for Public Health Services Development – October 19, 2012** On October 19, the State Council issued the 12th Five-Year Plan for the development of public health services. The plan specifies targets such as attaining a basic health care system covering urban and rural residents by 2015, supporting the development of private hospitals, increasing the average life expectancy by one year from the 2010 level, and controlling the "unreasonable growth of medical costs."
- MOH issues action plan on hospital infections** The Ministry of Health (MOH) released the Action Plan for Preventing and Controlling Hospital (Nosocomial) Infections (2012-2015). According to the notice, by the end of 2015 all Level III and Level II hospitals must meet health standards in their key departments. The notice also requires all hospitals to implement infection prevention and control measures, including disinfection and quarantine, and attain a sterilization rate of 100 percent

Events

- On December 4, 2012 from 10:00 a.m. – 2:00 p.m., Reed Smith's DC office is hosting a program entitled:

“The Basics of Chinese Medical Device Regulation and Approvals and the Role of Shanghai’s Municipal Food and Drug Administration”

Speakers: Shanghai Municipal Food and Drug Administration’s Feng Lin, Director of Medical Device Registration (Shanghai) and Nicole Taylor Smith, Assistant Country Director, U.S. FDA China Office (Beijing)

Feng Lin will provide an overview of SMFDA regulation of medical devices and will identify priority regulatory issues for medical devices, including registration. The program will be conducted in Chinese and English and supported by a translator, and will include a question and answer session.

To register to attend, please contact Jill Himelfarb at jhimelfarb@reedsmith.com or 202 414 9417.