ReedSmith

Client Alert

Life Sciences Health Industry Group

China Life Sciences Health Industry Client Briefing - December 2012 (January 18, 2013)

If you have questions or would like additional information on the material covered in this Alert, please contact the author:

Jay J. Yan
Partner, Shanghai
+86 (21) 6032 3166
jyan@reedsmith.com

John J. Tan
Counsel, Shanghai
+86 (0)21 6032 3126
jtan@reedsmith.com

Mao Rong
Counsel, Beijing
+86 10 6535 9500
mrong@reedsmith.com

Katherine Yang
Associate, Beijing
+86 10 6536 9542
kyang@reedsmith.com

May Wong
Associate, Hong Kong
+852 2507 9702
mwong@reedsmith.com

Vicki Lung
Associate, Washington, D.C.
+1 202 414 9281
vlung@reedsmith.com

Gordon B. Schatz
Partner, Shanghai/ Washington, D.C.
China: +86 1350 109 1380
D.C.:+1 202 414 9259
gschatz@reedsmith.com

…or the Reed Smith lawyer with whom you regularly work.

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

- **Industry Calls for Reform of Lagging Drug Review System (*Global Times* 2012-12-02) – December 3, 2012** A reform of China's drug review system is necessary in order to hasten pharmaceutical innovation, industry experts advised during a forum held in Beijing in early December. A report recently released by the Research and Development Pharmaceutical Association Committee (RDPAC), an organization that represents 37 leading pharmaceutical companies in China, indicates that access to innovative drugs in China generally lags four to eight years behind that in other countries. This is based, in part, on the protracted review process in China, as well as the limited capacity of the reviewing body.

- **Four Governmental Authorities to Take Measures to Upgrade Good Manufacturing Practices (GMPs) (Economic Information Daily 2012-12-04) – December 4, 2012** Four governmental authorities, including the State Food and Drug Administration, the National Development and Reform Commission, the Ministry of Industry and Information Technology, and the Ministry of Health, will jointly issue a Notice Concerning Accelerating the Implementation of New GMP Requirements and Upgrading the Pharmaceutical Industry. This notice will require drug manufacturers to fulfill the new Good Manufacturing Practices (GMP) requirements by the end of 2016. China will implement six measures that are aimed at supporting the drug manufacturing industry, including: (i) encouraging M&A among drug manufacturers; (ii) strictly examining and approving the qualification of commissioned production

enterprises; (iii) establishing a drug manufacture elimination mechanism; (iv) setting and adjusting drug prices by considering the interests of qualified GMP manufacturers; (v) introducing upgraded policies for drug bidding and tendering; and (vi) supporting qualified drug manufacturers in their efforts to construct preparation production lines that are aligned with international standards.

- **Chinese Manufacturers of Sterile Drugs Struggling to Meet New GMP Deadline (Xinhua News Agency 2012-12-14) – December 14, 2012** About 17 percent of China's sterile drug producers may fail to meet a deadline to qualify for China's new Good Manufacturing Practices (GMP) requirements for drugs, according to an official survey published in mid-December. The survey, conducted by the State Food and Drug Administration, indicates that although China has 4,462 production lines of sterile drugs in 1,319 enterprises, only 23 percent had planned to adapt to the new GMP standards by the end of 2012, and only 60 percent of them intend to do so by the end of 2013, which is the legal deadline.

- **Pharmaceutical Market to Hit 2.3 trillion Yuan by '20 (Xinhua News Agency 2012-12-31) – December 31, 2012** China's pharmaceutical market is expected to soar to 2.3 trillion yuan ($369.2 billion) by 2020, up from 926.1 billion yuan in 2012, according to a report published by the *Social Sciences Academic Press.* The Report on China's Pharmaceutical Market 2012 observes that China's aging population will likely increase demand for medicine, while the fast-growing economy is expected to boost both social insurance levels and consumption capacities. According to the report, these factors will help China's pharmaceutical market expand at an average annual rate of 12 percent by 2020.

- **China Announces 17 New Device Classifications (RF Regulatory Focus 2012-12-21) – December 31, 2012** On December 10, 2012, China's State Food and Drug Administration (SFDA) issued a notice to the provinces and autonomous regions announcing the classification of 17 medical devices. These classifications were derived from expert advice provided to the SFDA. Among the newly classified devices, two of the products will be regulated as Class III (high-risk) medical devices: an ultrasound tumor therapy system and a diagnostic imaging device for the skin.

A. Two devices subject to Class III (high-risk) administration
   1. Ultrasound tumor therapy system (超声肿瘤治疗系统)
   2. Diagnostic imaging device for the skin (皮肤镜图像诊断仪)

B. Ten devices subject to Class II (moderate-risk) administration
   1. Pressure distribution measurement cushion (压力分布测量垫)
   2. TCM sweating detector (中医汗出检测仪)
   3. Medical image processing software (医学影像处理软件)
   4. Fluorescence imaging and graphic reporting software (荧光成像和图文报告软件)
   5. Ventilator heated expiratory filter (呼吸机呼气加温过滤器)
   6. Medical laser fiber (医用激光光纤)
   7. Cochlear implant signal converter (人工耳蜗信号转换器)
   8. Device for measuring contrast sensitivity with glare (带眩光的对比敏感度仪)
   9. Choledochofiberscope (纤维胆道镜)
   10. Ultrasound breast imaging diagnostic device (超声光散射乳腺诊断系统)

C. One device subject to Class I (low-risk) administration
   1. Ophthalmic surgery observation device (眼科手术非接触观察装置)

D. Four devices exempted from administration as medical devices
   1. Efficient medical injection head processor (医疗用注射头高效处理器)
   2. One-stop flushing fluid processing system (一站式冲洗液生产系统)
   3. Medical air cleanser (医用空气清净机)
   4. Mobile cart (移动推车)

- **Hong Kong, Macao Health Providers Allowed to Set Up Mainland Health Institutions (Xinhua News Agency 2012-12-08) – December 10, 2012** The Ministry of Health recently announced that Hong Kong and Macao health service providers may establish health institutions in mainland China beginning January 2013. Providers may set up health institutions that are wholly owned, jointly invested, or part of cooperative partnerships with other health establishments or enterprises in mainland China. Except for wholly owned hospitals or senior houses, the other forms of newly established entities will be subject to administrative approval by health authorities at the provincial level, rather than at the national level, which will, according to the MOH, result in simpler procedures.

- **Smaller Hospitals "Offer Huge Opportunities" (*China Daily* 2012-12-13) – December 13, 2012** A recent study reports that China's county-level hospitals and community health care centers "offer huge opportunities" for multinational and local pharmaceutical companies. The study, which was conducted by global management and business strategy advisory firm Boston Consulting Group, was based on more than 60 in-person interviews and 900 detailed surveys provided by hospital heads, physicians and patients. According to

the report, China's 10,000 county-level hospitals, with their huge patient population base and potential for rapid growth, hold the greatest opportunities for pharmaceutical companies.

- **White Paper on Medical and Health Services in China (*China Daily* 2012-12-27) – December 27, 2012** For the first time, the State Council Information Office of the People's Republic of China published a white paper on medical and health services in China. The white paper, which is divided into nine parts, reports that China's total expenditures for health care in 2011 reached approximately RMB 2.4 trillion (US$390 billion), accounting for about 5.1 percent of China's GDP. The white paper also observes that in China, the average life expectancy has reached 74.8 years. The white paper acknowledges the contributions of the latest round of health care reform in China, as well as other improvements enacted within the health care sector. These include an overview of health care reform; infectious disease prevention and treatment; prevention and treatment of chronic, non-communicable disorders; health emergency management; protecting women's and children's health. And traditional Chinese medicine.

- **Reed Smith's China Device Regulatory Briefing – December 4, 2012 – Practical Tips** On December 4, 2012, Reed Smith held a regulatory briefing on China's regulation of medical devices. Speakers included officials from the Shanghai Municipal Food and Drug Administration, as well as from the United States Food and Drug Administration's office in Beijing. The briefing informed the attendees about medical device development and registration requirements at both the regional and national levels. Attached is a summary of priorities, practical tips, and lessons learned from the briefing. (Please note that this summary was also included in last month's briefing, and is reprinted here.)