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China Life Sciences Health Industry Client Briefing - November 2012 (December 12, 2012)

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

Priorities, Practical Tips and Lessons Learned from Reed Smith's China Device Regulatory Briefing on December 4, 2012.

On December 4, 2012, Reed Smith held a briefing on China's regulation of medical devices. Speakers were from the Shanghai Municipal Food and Drug Administration and also from the US FDA Office in Beijing China. We've prepared a summary of the priorities of the agencies, practical tips and lessons learned by attendees.

To read the full summary, [click here](#).

News & Regulations

- **Programs of Designated Drug Production to be Initiated: Five to 10 Pilot Varieties to be Selected in First Batch (*Shanghai Securities News* 2012-11-13) – November 13, 2012** The Ministry of Health (MOH) will issue regulations regarding the designated drug production program, together with the Ministry of Industry and Information Technology, the National Development and Reform Commission, and the State Food and Drug Administration. Five to 10 scarce varieties will be subject to the unified national bidding and designated production after the issuance of the regulations. MOH will give the designated manufacturers a proper financial margin when setting the prices of those drugs. It is estimated that the exclusive varieties, scarce varieties and drugs for children in the essential drug list, will be produced by designated drug manufacturers by 2015.
- **Drug Firms Pursue Joint R&D (*China Daily* 2012-11-01) – November 1, 2012** For some time, Chinese drug companies that shipped drugs overseas considered themselves to be first and foremost Chinese companies engaged in international business. Multinational companies that came to China and just sold drugs or services

in China viewed themselves as multinational with China operations. Such distinctions, though, are becoming blurred in the pharmaceutical industry as more Chinese and multinational companies not only sell drugs across borders, but also conduct research and development with each other. Multinational drug companies have had joint ventures for some time. This trend seems to be increasing and diversifying. Xiang Jun, pharmaceutical researcher of Forward Business Intelligence, said China's pharmaceutical R&D outsourcing market was worth roughly \$4 billion in 2010, making it one of the largest in the world. And it has been growing at an annual rate of about 25 percent in recent years.

- **Drug Makers and the Unpredictability of Drug Development (*China Daily* 2012-11-07) – November 8, 2012** Western drug companies have been viewed as contributing many advances in new drugs and in health care. Western-based multinational pharmaceutical corporations have created drugs that save lives, cure illnesses, and improve physical and mental well-being. Drugs can extend the length and quality of a person's life. Chinese drug companies have seen some of the benefits of how western companies develop drugs and commercialize them. Drug makers can generate substantial revenues by securing patent and IP rights for innovative drugs. This is important because research and development (R&D) of new drugs is costly and unpredictable. Scientific experiments don't guarantee good results. Furthermore, some drugs that receive significant financial support in early development, may not in the short-term generate favorable clinical results, or do not obtain approvals from government agencies. Chinese drug companies face these challenges in China and throughout the world. They need to be prepared at early stages in drug development to obtain needed data, and understand and comply with applicable regulations that will secure IP rights and enable approvals in China and worldwide.
- **New Draft Regulations on Stem Cell Industry to be Issued (*China Securities Journal* 2012-11-05) – November 5, 2012** This year, a stem cell clinical research expert committee completed the drafts of three regulations on the clinical application of stem cell, which include the Guiding Principles on Clinical Research of Stem Cells, the Administrative Measures on Stem Cell Clinical Research Institutions, and the Administrative Regulations on Quality Control for Stem Cell Drugs and Guiding Principles on Stem Cell Pre-clinical Research. According to the drafts, stem cell clinical applications will be subject to similar regulatory models as new chemical and biological drugs. The stem cell clinical research would also consist of Phases I, II and III. According to an expert in this area, the required number of case studies would be reduced under the draft regulations. The stem cell cannot be used for patient clinical care/treatment before obtaining the clinical approval. The three regulations noted above also went through the comment collection and further amendment process this September. They are expected to be issued soon, but no specific timetable is announced. Industry experts believe that applications for stem cell clinical research may be accepted by relevant authorities in the first half of next year.

- Approval from the State Food and Drug Administration concerning Drug Registration and Appraisal Reform on Pilot Basis in Guangdong Food and Drug Administration – November 13, 2012** State Food and Drug Administration (SFDA) indicated November 2 that it approved Guangdong Province to assume drug evaluation and approval responsibilities on a pilot basis. In accordance with Article 172 of the Measures for the Administration of Drug Registration, the Guangdong Food and Drug Administration is authorized to conduct evaluation and review for technology transfers relating to the new drugs and the drug manufacturing within Guangdong province. Then, the SFDA will issue drug approvals based on the review results made by the Guangdong Food and Drug Administration. The Guangdong FDA is also authorized to approve the applications for contract manufacturing of drugs (except biological products and traditional Chinese medicine injections) if the contractor is located within Guangdong province. But such approvals shall be filed with SFDA. The notice further stated that Guangdong local authorities shall develop their implementation rules in compliance with the existing drug registration laws and submit such implementation rules to SFDA for approval before they are adopted.
- MOH Stresses Monitoring Medical Costs in New Announcement (Xinhua News Agency 2012-10-31) – November 13, 2012** Ministry of Health (MOH) released an announcement October 31 on medical costs in 2012, calling for local authorities to monitor the rising costs of specific diagnoses and treatments. According to the statement, MOH aims to strengthen the central procurement system for medical supplies, as well as the supervision of Class II and Class III clinical trials. The notice also calls for the close cooperation and division of work between public hospitals and primary health institutions.
- Health Insurance Policy Seen as Essential to Medical Alliance (China Daily 2012-11-08) – November 8, 2012** As Beijing's Chaoyang Hospital prepares to establish an alliance with other medical institutions, individuals involved in the project said the hospital will find itself under less pressure only if changes are made to public health insurance policies. The alliance, which involves four hospitals and seven community health care centers in Chaoyang district, is meant to encourage more people to seek treatment at small institutions. That will enable those small institutions to concentrate on chronic ailments, and large hospitals to mostly treat more complicated conditions.
- PRC to Allocate RMB 27.26 Billion to Support Public Health Services for 2013 (Yicai 2012-11-06) – November 13, 2012** The PRC central government has recently allocated RMB 27.26 billion in special funds to subsidize public health services in 2013, according to the Ministry of Finance (MOF) November 6. The funds will be used to support local governments in offering basic public health services, prevent and treat major infectious diseases, provide subsidies for pregnant women in rural areas, and subsidize cataract operations for patients.
- Chinese Company Devising Ways to Sell Medical Devices Abroad (China Daily 2012-11-27) – November 27, 2012** Chinese health care equipment maker Mindray continues to gain recognition overseas, according to Cecily Liu in London. David Yin, managing director of the Shenzhen-based Mindray Medical International Ltd. for Europe, recalled

that his first order from overseas was the result of “an accident.” In 2000, a British company’s attention was caught by the “made in China” label displayed on Mindray products at Medica, a trade fair in Germany. The company, which Mindray declined to identify, took the product to a British hospital for a quality assessment and bought it after being assured that it was up to standard. Mindray is now a large player in the medical devices industry, exporting products to 190 countries and regions. In 2011, it had \$881 million in net revenue, more than half of which was generated overseas.

- **Edwards Wins Chinese Approval for Perimount Mitral Valve (MassDevice 2012-11-29) – November 29, 2012** Medical device giant Edwards Lifesciences (NYSE:EW) reported on the China State Food & Drug Administration (SFDA) approval for its Carpentier-Edwards Perimount replacement mitral heart valve, part of the Perimount suite of devices that Edwards says are “the world’s most frequently implanted valves for more than 30 years.” Made of bovine pericardial tissue, the Perimount mitral valve has been in clinical use since 1984 and features proprietary ThermaFix anti-calcification processing. The device has been on the market in the United States since 2000, and also has CE Marking for European distribution.
- **Nestlé in Chinese Medicine Deal with Li Ka-Shing’s Firm (BBC 2012-11-29) – November 30, 2012** The market for traditional Chinese medicine has seen robust growth in recent years. Nestlé will set up a joint venture with Hutchison China MediTech, controlled by Hong Kong billionaire Li Ka-Shing. The deal will give Nestlé access to more than 50,000 extracts used in the manufacture of Chinese medicines.

Events

- **Singapore to Ease Licensing of Class A Devices from 2013 (Clinica 2012-11-28) – November 27, 2012** The Health Sciences Authority in Singapore released draft guidance on new standards for licensing Class A medical devices. The new rules, which are part of a revised quality management program set to go into effect in January, will no longer require wholesale dealers and importers of Class A devices to receive third-party audits or certification when licensing their products.