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Life Sciences Health Industry China Briefing

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Life Sciences Health Industry China Briefing summarizes the business, regulatory and legal developments during August 2011 in China important for drug, device, and life science/health care companies.

Pharmaceutical Devices, Health Care & Life Sciences

News

- **MOH Registration Time in Hospital to be Held Under 10 Minutes (Beijing Times 2011-08-01) - August 1, 2011**
  The Ministry of Health (MOH) released a service indicator standard that requires hospitals to make reasonable arrangements for outpatient and emergency services. Waiting time for registration, cost calculation, payment processing and dispensation of medicine is not to exceed 10 minutes.

- **Ministry of Public Health Solicits Public Comment on Administrative Measures on Clinical Application of Antibiotics (China Legal Information Center 2011-08-04) - August 9, 2011**
  On August 3, the Ministry of Public Health released Administrative Measures on Clinical Application of Antibiotics for public comment. The Measures are expected to impose limiting conditions on the use of antibiotics in medical institutions, and have been referred to within the industry as the most stringent legislation regulating antibiotic drugs. Reporters realized yesterday in comparing the most recent draft to that issued July 1, that the new draft does not explicitly limit the number and variety of antibiotics hospitals can purchase. The new draft does, however, place antimicrobial drugs in a special class and imposes special constraints on their use.

- **China, US Plan to Work Together on Product Safety (China Daily 2011-08-09) - August 9, 2011**
  China and the United States have reached a consensus on tapping the potential of cooperation to

improve the quality of Chinese consumer goods through more training programs for manufacturers, said officials from both sides. "We would like the Chinese industries to move from focusing on specific product safety issues to a broader, long-range view about the reputation of Chinese products," said Richard W. O'Brien, director of International Programs and Intergovernmental Affairs of the US Consumer Product Safety Commission (CPSC).

- **Shanghai Pharma Looks Overseas (China Daily 2011-08-17) - August 17, 2011**
  Shanghai Pharmaceuticals Holding Co., which has almost $2.5 billion in cash, may make its first acquisition outside China by the end of the year, spurred by a plunge in pharmaceutical stocks and a stronger yuan. Targets may include mid-sized drugmakers in the United States or Europe that would help the Shanghai-based company, China's second-largest drug distributor, expand its portfolio of medicines, Chairman Lu Mingfang told reporters on a conference call Monday. He didn't identify any candidates. Overseas purchases are becoming cheaper after shares of health care companies slumped in Europe as the region's sovereign debt crisis deepened, and as investors in the United States speculated the economy may contract. Since 2010, Shanghai Pharma has bought, or agreed to make, at least nine acquisitions to expand its distribution business.

Regulations

- **Notice from the Ministry of Health on the Circulation of the 2011 Amendment to the Administrative Regulations on Reporting Health Supervision Information - August 11, 2011**
  The Ministry of Health recently revised the Administrative Regulations on Reporting Health Supervision Information, originally issued in 2007. The revised regulations comprise 29 articles addressing reporting responsibilities, the reporting system, the usage and management of information, information safety and evaluation, and protective measures, among other topics.

- **Notice on Soliciting Comments on the Draft Catalogue of Class II Medical Devices Exempted from Clinical Trial Documentation Requirements - August 17, 2011**
  The SFDA has recently determined that clinical trial documentation will no longer be a prerequisite for the registration of 21 kinds of Class II medical devices. The selected devices have been on the market for several years and feature mature production processes. The SFDA prepared the Catalogue with input and comments from relevant entities in order to improve administrative efficiency. Comments were accepted by mail or through electronic delivery until August 31, 2011.

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- **Notice on the Recategorization of 48 Kinds of Prescription Drugs as OTC Drugs - August 18, 2011**

  The State Food and Drug Administration issued a notice announcing that 48 kinds of prescription drugs, including eight chemical drugs and 40 traditional Chinese medicines, will be recategorized as OTC drugs. OTC instructional templates are also provided in the notice. Instructions and labels associated with these drugs will be changed in accordance with the Notice on Detailed Rules for OTC Instructions.

- **Notice from the General Office of the Ministry of Health on the Expansion of Pilot Projects for Physicians' Practice in Multiple Cities - August 18, 2011**

  Physicians in certain areas and meeting certain requirements may practice medicine in up to three cities. The program's pilot areas include public hospital reform pilot cities and two prefecture-level cities in each province, autonomous region and municipality. Interested physicians shall apply for a multi-regional practice certification with relevant health management authorities and, if successful, may be granted additional practice areas on their Physician Practice Certificate.

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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.

This Client Alert was compiled up to and including September 2011.