

China Briefing - Developments During September 2011

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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

- **Swiss Drugmaker Novartis Expands in China (CNTV 2011-09-05) - September 6, 2011**

Swiss pharmaceutical giant Novartis is pouring investment into China, by way of the US\$1.6 million "Health Express" initiative in Xinjiang. The program provides hygiene and health education to students, health care professionals and patients. Novartis is also undertaking a training program for medical professionals, focusing on the prevention and treatment of hepatitis B in underdeveloped regions.

- **China Plans to Divide Emergency Patients into Four Classes for Medical Treatment (*China Youth Daily* 2011-09-07) - September 8, 2011**

The Ministry of Health issued draft Guiding Principles for the Classification of Emergency Patients' Illnesses for public comment. Hospitals are required to classify the medical treatment of emergency patients based on the severity of their illnesses. Patients will be divided into four classes, with priority treatment given to those with the most serious illnesses. Class I patients are considered endangered, and hospitals are instructed to reasonably allocate medical staff and medical resources to save such patients. Class II patients are critically ill and are to be treated as soon as possible. Class III patients are to be treated urgently, while Class IV patients are not considered urgent cases.

- **China's Biopharmaceutical Industry to Accelerate Internationalization (Caijing 2011-09-13) - September 13, 2011**

The 12th Five-Year Plan for the biopharmaceutical industry will be issued after the Mid-Autumn Festival. The following four changes are to be implemented in the 12th Five-Year Plan period: (i) 25 innovative medicines will enter production; (ii) internationalization will accelerate, with sales to the EU, U.S. and Japanese markets emphasized; (iii) the level of quality guarantees will be raised; and (iv) enterprises will undergo restructuring. Currently, 24 enterprises have obtained EU

or U.S. sales certificates. China will have more than 200 generic pharmaceuticals registered or sold in developed countries during the 12th Five-Year Plan period.

- **MOH Surveys Clinical Application of Antimicrobials (www.cnpharm.cn 2011-09-13) - September 13, 2011**

The Ministry of Health has organized experts to carry out a special administrative oversight investigation into the clinical application of antimicrobials in Beijing and another 21 provinces. Health authorities' provincial-level inspections will be focused on determining the potential effectiveness of (i) the establishment of a training program for the clinical application of antimicrobials; (ii) an antimicrobial monitoring network and bacterial resistance monitoring network; and (iii) investigation of illegal conduct by medical institutions and staff. Inspection of medical institutions will focus on their effectiveness in (i) drafting and implementing a training program; (ii) granting qualified physicians the right to prescribe antimicrobials; (iii) providing guidance on prescription levels to physicians; and (iv) releasing details on physicians prescribing drugs irregularly and statistics on the usage of antimicrobials.

- **Medtronic Opens Orthopedic R&D Center with Weigao (Xinhua News Agency 2011-09-15) - September 15, 2011**

The international medical equipment company Medtronic, Inc. is speeding up its business localization in China with the opening of a research and development (R&D) center in partnership with Shandong Weigao Group Co Ltd, the two announced in Beijing September 14. The Medtronic-Weigao Orthopedic Technological Support Center, involving a 20 million yuan (\$3.13 million) investment in R&D equipment, will focus on the development of orthopedic technologies and devices, mainly to fill local Chinese needs.

- **DHL Establishes Second Life Science and Health Care Logistics Center in Beijing (Caijing 2011-09-22) - September 22, 2011**

On September 21, 2011, DHL announced the establishment of a second life science and health care logistics center in Beijing. According to DHL, China will become the fifth-largest drug exporting country, with an emphasis on exporting active pharmaceutical ingredients (API) and relevant products. The center's 140 sq. meter temperature control room is equipped with electronic temperature data, an alarm system, and other life sciences temperature-sensitive storage equipment. The center will provide cold-chain transportation satisfying supervision standards, and will maintain the highest safety and quality standards for domestic drug manufacturers and biotech companies.

- **Outpatient Appointments to be Available at All Class-A Hospitals Before 2012 (Xinhua News Agency 2011-09-22) - September 23, 2011**

According to the Ministry of Health, all class-A hospitals nationwide shall provide outpatient

appointment services for patients by the end of December and no less than 85 percent of doctors performing these services shall have expert qualifications. By next summer, that proportion is to rise to 100 percent. The Ministry of Health introduced outpatient appointments starting in 2009 and involving more than 1,200 class-A hospitals, as well as some class-B hospitals. Appointment platforms and methods have been gradually standardized over the past two years.

- **Beijing to Provide Essential Drugs to Patients with Serious Mental Illnesses (Xinhua News Agency 2011-09-22) - September 23, 2011**

Beijing will revise Implementation Measures for the Law on the Protection of Disabled Persons and will provide essential drugs to patients with serious mental illnesses free of charge. Beijing will also encourage nonprofit organizations to establish kindergartens for disabled children in order to provide psychological rehabilitation, promote intellectual development, and offer physical instruction and training to such children.

- **Cardinal will Continue Acquisitions in China (*China Daily* 2011-09-27) - September 27, 2011**

Pharmaceutical wholesaler Cardinal Health Inc. said it is looking for more acquisition opportunities in China after its \$60 million purchase of distributor Zuellig Pharm China last year. Buying out Zuellig, which had \$1 billion in sales and distribution to about 49,000 hospitals and clinics, helped the U.S.-based company establish a foothold and expand services in China.

- **TCM Makers Lack IPR Awareness (*Global Times* 2011-09-29) - September 29, 2011**

Many Chinese pharmaceutical companies, not aware of the full scope of intellectual property rights (IPR), are finding the rights to traditional Chinese medicine (TCM) are being acquired in China by foreign companies, Wang Ying, vice chairman of the China Association of Traditional Chinese Medicine, said recently. As a result of underdeveloped intellectual property right management regarding TCM, some pharmaceutical enterprises have used their available capital and well-developed pharmaceutical technologies to obtain the intellectual property rights.

Regulations

- **Notice on Circulation of the Guidelines for Monitoring Adverse Events Involving Medical Devices (for Trial Implementation) - September 20, 2011**

The Guidelines, issued by the State Food and Drug Administration September 16, 2011, clarify stakeholders' obligations and responsibilities; establish requirements for monitoring departments, staff, and a monitoring system; and delineate work procedures for medical device manufacturers, distributions, end-user entities, and local and state adverse event monitoring institutions, respectively. The SFDA also encourages citizens, legal persons and other social organizations to accurately report such events.

- **Letter on Soliciting Public Comments on Communication Methods for Responsible Food and Drug Safety - September 29, 2011**

The State Food and Drug Administration issued the draft September 26, and public comments will be accepted until October 25. The communication in the measures refers to communication between food and drug management authorities; developers, producers and manufacturers of drugs, medical devices, health foods, and cosmetics; medical institutions; and catering services, in order to control food and drug quality risks, troubleshoot problems, and identify the causes of problems. Communication can be unilateral or collective. Communication participants, content and procedures are also provided in the measures.

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