

Life Sciences Health Industry China Briefing

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

News

Tianjin Pharma Firm to Build Base in US (*Global Times* 2011-06-03) - June 3, 2011

Tianjin-based pharmaceutical company Tasly Group is investing \$40 million to build a production and training center in Maryland to help prepare for the entry of its Compound Danshen Dripping Pills (CDDP) into the American market, the company announced in Shanghai on Thursday. The 430,000 sq. ft. facility is expected to be complete within a year-and-a-half, and will serve as a base for further clinical trials of CDDP, as well as its future production, packaging and warehousing.

Media Forces Drug Firm to Act (*Shanghai Daily* 2011-06-09) - June 9, 2011

Media exposure of environmental contamination has forced Harbin Pharmaceutical Group Co. to reduce or even stop production until the company takes steps to solve the problem. The drug-maker admitted in a statement to the Shanghai Stock Exchange that it has "problems" in discharging waste water and incineration of industrial wastes. It agreed to cut back on production until its water processing system, which has been under repair since March, becomes operational in the middle of this month.

Drug Firm Inks Deal to Build New Plant (*Xinhua News Agency* 2011-06-15) - June 15, 2011

Harbin Pharmaceutical Group yesterday signed an agreement to build a new production plant following a recent pollution scandal that erupted over its waste emissions. The agreement was signed with Harbin's Acheng District government. The first phase of the project is scheduled to be completed in 2013, with a planned investment of 2 billion yuan (US\$309 million), according to the agreement.

Foreign Hospitals Eye China Opportunities (*Global Times* 2011-06-21) - June 22, 2011

With health becoming the top priority for the Chinese people, foreign hospitals are seeking to capitalize on the need for better health care services and information, which is not fully met by public hospitals, experts said yesterday. Many Chinese people turn to the Internet for health-related information because doctors at public hospitals, who are mostly specialists, do not have enough time to communicate with their patients, Alan R. Kahn, a group vice president of United Family Healthcare, said at a forum held in Beijing by the American Chamber of Commerce in China.

China to Release Its Biomedical Plan (*China Daily* 2011-06-24) - June 28, 2011

The National 12th Five-Year Plan (2011-2015) for Biomedical Industry Development will soon be released, the *Shanghai Securities News* reported Friday. The plan has been drafted by the National Development and Reform Commission (NDRC). As one of the strategic emerging industries, biomedicine is a very important part of the biotech industry, and by 2015 the market size is expected to reach \$100 billion, while the biotech industry more generally will add another \$200 billion of output.

China Plans to Expand Pilot Medical Insurance Program for Rural Children (*USCBC update* 2011-06-30) - June 30, 2011

On June 28, Health Minister Chen Zhu stated that China plans to expand a pilot medical care project to all rural areas by September to give increased financial assistance to children with congenital heart disease and leukemia. By September, all rural children who have joined the New Rural Cooperative Medical Care System, a medical insurance plan for villagers, will be eligible for more than 70 percent reimbursement for the costs involved in treating these diseases. The government launched the pilot project in 15 provincial-level regions in June 2010 to provide larger reimbursement for medical bills to rural children with critical diseases such as congenital heart disease and leukemia, and the project succeeded in cutting their medical expenses by about 60 percent. The project helped 9,059 children get medical treatment for these illnesses as of April. China's new rural cooperative medical care system now covers 832 million people, or more than 96 percent of the rural population. Under the plan, the government and a farmer jointly contribute RMB 300 in premiums each year, which then allows farmers to be reimbursed for about 70 percent of their inpatient costs.

China Vows to Staff Clinics with Qualified General Practitioners (*USCBC update 2011-06-30*) - June 30, 2011

China on June 22 vowed to staff all hospitals with qualified general practitioners by 2012. At an executive meeting of the State Council presided over by Premier Wen Jiabao, it was decided that China will establish a system of general practitioners. The move is expected to ease public complaints about the difficulty of accessing affordable, high-quality medical services in local clinics. China will work to ensure that for every 10,000 urban or rural residents, two to three qualified general practitioners will be ready to take care of their health problems. In this case, "qualified" is defined as having completed a five-year bachelor degree program in clinical medicine and three years of specialized medical education before becoming a general practitioner, the statement said. In order to make up for the shortage of qualified general practitioners, selected medical practitioners who are already working for local medical institutions will be allowed to transfer to general practitioner posts after completing one to two years of additional training. Authorities will also introduce fresh stimulus programs for general practitioners, including offering subsidies for doctors willing to work in remote and underdeveloped regions. According to the statement, government departments and local authorities are urged to work out concrete plans and regulations to achieve the government's goal of providing high-quality health care.

MOH and the Ministry of Finance (MOF) Launching a Team of Experts to Examine Public Health Services in Local Regions (*USCBC update 2011-06-30*) - June 30, 2011

MOH and MOF announced June 20 they will launch a team of experts to conduct exams in local regions on national basic public health services, in a bid to ensure the benefits of project funds, and promote basic public health services. The national basic public health services project was launched in June 2009, and has covered 1.3 billion people and is highly relevant to the health and life of the nation's population. It has mainly focused on existing residents' health, and targeted children, pregnant women, senior citizens and people who suffer from chronic disease. The project offers free basic public health services and currently includes 10 categories covering 41 items.

China's Ministry of Human Resources and Social Services (MOHRSS) Issued Opinions on Medical Insurance and Outpatient Planning, and Promoting Insurance Payment Methods (*USCBC update 2011-06-30*) - June 30, 2011

MOHRSS on June 14 released the Opinions on Basic Medical Insurance and Outpatient Planning for Urban Residents (Opinion 1), and the Opinions to Promote Medical Insurance Payment Methods

(Opinion 2). Opinion 1 emphasizes local policy to be drafted for later implementation. Medical insurance should cover at least 50 percent of medical expenses at local medical centers. Outpatient insurance mostly covers frequently occurring diseases and chronic diseases. Opinion 2 mentions that for outpatient expenses, appropriate ways should be adopted in line with the requirements of local medical centers. In terms of inpatient expenses, various disease types should be taken into consideration for insurance coverage.

Researchers Hopeful of Chinese Remedy for UK Drugs Industry (*Financial Times* 2011-06-30) - June 30, 2011

The Medical Research Council is in advanced talks with Chinese authorities to attract up to £500 million in investment to the UK over the next five years in an innovative partnership that could save 850 scientific jobs. Discussions center on a new drug development company that would salvage employment at British pharmaceutical research facilities earmarked for closure.

Regulations

Notice from the Ministry of Health on Approval and Management of Non-Public Medical Institutions - June 9, 2011

The Ministry of Health issued the Notice May 31 addressing several issues regarding non-public medical institutions, including:

- Relaxing controls on social investors' access to medical institutions
- Relaxing controls on the medical practice scope for non-public institutions
- Further integrating non-public medical institutions into the health care system
- Involving experts from non-public medical institutions in industrial associations and other management organizations
- Encouraging non-public medical institutions to undertake social responsibilities
- Guiding non-public medical institutions to enhance clinical service
- Managing the clinical application of medical technology in non-public medical institutions
- Strengthening practice guidelines for non-public medical institutions
- Integrating industrial associations in the supervision of non-public medical institutions
- Strengthening the supervision and administration of non-public medical institutions

Administrative Measures on Recall of Medical Devices (for Trial Implementation) - June 13, 2011

On May 20, 2011, the State Food and Drug Administration issued the Measures on recall of medical devices in connection with potential product defects. The Measures require medical device manufacturers to issue warnings, examine, repair, re-label, or modify products in response to assessment of potential or observed defects or failure to function. The Measures also call on manufacturers to improve specifications; upgrade software; and change, recall, or destroy certain categories, types, or batches of products on sale. The measures set forth general principles and procedures for the investigation and evaluation of defects of medical devices, and alternative actions including voluntary and mandatory recall, along with legal liability for manufacturers.

Notice from the General Office of the Ministry of Health on Publication of List of Institutions for the Examination of Class III Medical Technology - June 14, 2011

The Ministry of Health released the notice designating four institutions as examiners of Class III medical technology June 13. The designated institutions include Chinese Medical Association, Chinese Hospital Association, Chinese Medical Doctor Association and Chinese Stomatological Association.

Notice on Circulation of the "2011 Guideline for Clinical Care" - June 24, 2011

The Ministry of Health issued the Guideline to regulate clinical care and improve services. The Guideline is divided into 17 chapters with topics including hygiene and comfort management, nutrition and excretion care, physical activity management, care for common symptoms, specimen collection, and physical assessment techniques, among others.

Notice Concerning Extension of Drug GMP Certificate - June 30, 2011

SFDA on June 20 issued the Notice on Renewal of Drug GMP Certificate. All enterprises that hold an expired Drug GMP Certificate and do not meet the requirements under the Administrative Regulations of Drug Production and Quality (revised 2010), must submit a self-evaluation report. Provincial FDAs should, per the Administrative regulations, critique the reports and provide feedback in written form. For qualified enterprises, renewal of the old certificate will be granted without issuing a new certificate. Information will be shared on provincial FDA websites and the SFDA website.



Notice on Stoppage of Sale and Use of Amoxicillin and Clavulanate Potassium Manufactured by GlaxoSmithKline Plc (GSK) - June 30, 2011

SFDA recently ordered the recall of an antibiotic medicine with a banned plasticizer, as public concern about plasticizer-tainted products builds.

Test results showed that Amoxicillin and Clavulanate potassium, manufactured by a major international drug company, appear to contain traces of DIDP, which is used mainly as an additive in plastics to make them more flexible, said an online statement issued by the SFDA on Saturday. The Chinese SFDA administration ordered the immediate halt of its sale and use, and recalled any of the products that had entered the mainland market. The amount of the chemical found in the prescription was not specified. Local drug authorities were told to enhance their supervision and inspection.

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