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China Life Sciences and Health Care Industry Alert

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CHINA BRIEFING February 2012 (March 13, 2012)

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

Regulations

- **State Council Releases the 12th Five-Year Plan on Drug Safety and Standards**
  On January 20, 2012, the State Council issued the 12th Five-Year Plan directing ways to improve drug safety, comply with international standards, and better regulate medical devices and pharmacies. These directives are intended to protect people's health, and encourage the development of the pharmaceutical industry. The plan addresses the following:
  - Compliance with basic standards, including harmonization with international standards by all chemical medicines and biological products
  - 90 percent of medical devices shall adopt international standards.
  - Generic drugs on the national essential drugs list or commonly used in clinical settings shall meet international standards. This covers drugs approved for production before the implementation of the Administrative Measures on Drug Registration revised in 2007.
  - 100 percent of domestic drug production shall meet the requirements stipulated in the revised 2010 drug GMPs.
  - 100 percent of sterile and implantable medical devices shall meet the requirements of medical device GMPs.
  - 100 percent of drug distributors shall meet the drug distribution GMPs/GDPs.
  - Newly opened retail pharmacies' hospital pharmacies shall have licensed pharmacists during the business time to guide patients to reasonably use drugs by 2015.

- **Concentrated Rectification Action in National Drug Manufacturing and Distribution Sectors – February 16, 2012**
  The State Food and Drug Administration ("SFDA") initiated a special rectification action to regulate the drug manufacturing and distribution market and to crack down on illegal and criminal activities from late February to late June. The rectification includes self-rectification of drug manufacturers and distributors and investigation by the authorities. The illegal activities will be subject to severe punishment.

- **Twelve Ministries: Crackdown on Serious Illegal Advertisement Broadcasting (China News Service, 2012-02-29) – February 29, 2012**
  Twelve Ministries, including the State Administration of Industry and Commerce, the Ministry of Health ("MOH"), and the State Administration of Radio, Film & Television, jointly initiated a special action to crack down on false and illegal advertising activities. The crackdown will focus on advertisements regarding medical treatment, drugs, healthcare, food, medical beauty services, and cosmetic products on radio, TV, in newspaper or other media. The medical institutions which refuse to rectify upon the receipt of two warnings will be subject to business suspension and even revocation of licenses. The channels may be shut down for broadcasting serious illegal advertisements. The drug administration authorities will include the illegally promoted products on a blacklist and forbid their sales.

- **Electronic Drug Supervision Plan from 2011 to 2015 – February 29, 2012**
  By the end of February 2012, anesthetic drugs, psychotropic substances, blood products, traditional Chinese medicine injections, vaccine, and all varieties of national essential medicines have been subject to electronic supervision. Having issued the plan on February 27, SFDA

plans to cover all kinds of medicines and high-risk medical devices in the electronic supervision system, and explore the feasibility of electronic supervision on raw materials by 2015. The whole process of manufacturing, distribution, and use of drugs by manufacturers, distributors, pharmacies, and medical institutions can be traced via the full-scale electronic supervision system. The electronic supervision will respond to the public's inquiries regarding the drug information, supervision code and authenticity of the medicines. The possibility of connecting the electronic supervision system and the medical insurance card system will be explored.

- **MOH Circulates the Administrative Measures on Health Card for Residents (for Trial Implementation) – February 3, 2012**
  According to the Notice issued by the MOH on December 30, 2011, domestic residents may apply for the resident health cards in certain qualified areas and use them in any medical institutions. The cards will include e-healthcare records and e-medical records and have expense settlement function.

- **MOH Circulates the Revised Diseases Classification and Code – February 3, 2012**
  The MOH revised the standards to strengthen the supervision on medical service information, improve the clinical management and accelerate the reform in relation to medical insurance expense settlements and payments. The trial period is one year. The local counterparts are required to implement the standards and provide in-time feedback.

- **State Administration of Traditional Chinese Medicine Circulates the Medical Device Allocation Standard of Traditional Chinese Medicine Hospitals (for Trial Implementation) – February 29, 2012**
  The Standard addresses the medical device allocation issues in Class A and Class B hospitals, respectively. The traditional Chinese medicine hospitals are required to purchase modern medical devices in line with the standard in order to improve the clinical effect. Ethnic medicine hospitals may purchase devices which have ethnic characteristics in compliance with the allocation standards.

News

- **MOH: Uniform Pricing and Production of Essential Drugs (Caijing, 2012-02-03) – February 3, 2012**
  The MOH issued the 2012 Health Work Points on February 2, which provide that China will implement unified pricing and designated production of essential drugs,that are in shortage and for children. The Work Points also encourage the e-transaction of drugs in the qualified areas. The government will reform hospitals at county levels. Approximately 300 hospitals in certain qualified counties with larger populations will carry out the pilot reform projects. The government will further improve the essential drug system, implement and revise certain regulations such as the Administrative Measures on the Use of Essential Drugs by Hospitals, the Clinical Application Guide for National Essential Drugs, and the National Essential Drug Formulary.

- **Price Increase Cap in Drug Distribution Chain to be Determined (China Business News, 2012-02-15) – February 15, 2012**
  The final draft of the Interim Measures on Drug Price Administration in Distribution Chain was recently issued for comment. The Measures, likely to be implemented on July 1, will impact around 20,000 enterprises. The Measures clarify drug price markups for drug distributors and hospitals, respectively, to prohibit unlawful sales commissions. According to sources, foreign companies and some domestic enterprises have responded by improving internal management as of last year, but many domestic enterprises may not yet have internal controls in place.

- **MOH: Diagnosis and Determination of Causation of Occupational Diseases (Caixin Media, 2012-02-03) – February 3, 2012**
  MOH is soliciting public comments on the revised Administrative Measures on the Diagnosis and Identification of Occupational Diseases. A laborer may request occupational disease diagnosis at the diagnosis institution where he is located, domiciled, and/or his place of residence. The diagnosis institutions shall not refuse such request. Three or more physicians are required to conduct the diagnosis and issue a certificate with the diagnosis details and results to the patient. If no evidence indicates that the symptoms of the patients were caused by factors other than the occupational risks, the causation between the occupational risks and symptoms of patients shall be established and the occurrence of the occupational disease shall be confirmed.

- **Pilot Reform Programs for Public Hospitals in Beijing to be Implemented this Year (Beijing Daily, 2012-02-06) – February 6, 2012**
  Beijing will initiate the pilot reform programs for public hospitals this year to implement the "separation of management and operation" and the "separation of prescribing and dispensing". The hospitals shall implement the "adjusted" systems of financial compensation and medical insurances and improve their corporate governance. Since the medical reform started three years ago, Beijing government has been increasing its budget and supervision in medical area; therefore, according to the government, the efficiency and quality of medical service has improved, and the individual medical expenses have decreased.

- **SPH Acquires Medical Raw Material Manufacturer (Caixin Media, 2012-02-06) – February 6, 2012**
  Shanghai Pharma (SPH) (601607.SH, 02607.HK) announced its acquisition of the 70 percent equity interest in Changzhou Kony Pharma Co., Ltd. ("Kony") and its planned acquisition of the remaining 30 percent equity interest in the next two years. Kony mainly manufactures medical raw materials and intermediates in anti-viral and cardiovascular sectors and exports half of its products overseas. SPH aims to expand its investment in medical raw materials to improve its pharmaceutical business chain. In the first half of 2011, Kony's revenue generated from the sale of certain key raw materials amounted to RMB 62.93 million with RMB 17.25 million net profit.

- **PE Industry Eyes Medical Investment (China Daily, 2012-02-29) – February 29, 2012**
  Softbank Asia Infrastructure Fund Partners, a private equity firm managing $4.5 billion yuan ($714 million) in funds, is set to beef up its presence in China's medical care industry. "We will continue to strengthen our efforts in this industry in the coming three to five years, given the ever-increasing social demand for health and higher standards of living, allied to the government's support for the medical care sector," said Xu Hang, a partner at SAIF. "At present, we have six teams working on related projects, from pharmaceuticals to medical care institutions," he said, adding that SAIF is a long-term investor and the money available for each of the investments ranges from $10 million to $100 million.

- **Beijing to Open Medical Service Market to Social Investors in Full Scale (China Securities Journal, 2012-02-10) – February 10, 2012**
  According to the draft Several Policies concerning Further Encouraging and Guiding Social Capital to Establish Medical Institutions, social capital is permitted to establish medical institutions. Social capital is encouraged to invest in non-profit medical institutions, medical institutions in suburban and country areas, medical institutions involving rehabilitation, nursing, traditional Chinese medicine, integrated traditional and western medicine services, and hospitals for minorities.

  The draft clarifies 18 policies in relation to issues such as market access, land use and taxes. Non-governmental social medical institutions and government-funded ones will implement the same basic medical insurance policies. Social capital-funded medical institutions which meet certain criteria will obtain the government's financial support.

- **TCM Exports Set to Rise at a Healthy Clip (China Daily, 2012-02-10) – February 10, 2012**
  The value of traditional Chinese medicine exported from China is expected to increase by more than 10 percent a year during the next five to ten years. The growth rate for the exports measured by weight is expected to increase from five percent to ten percent annually during the same period, Liu Zhanglin, vice-president of the China Chamber of Commerce for Import & Export of Medicines and Health Products, said. The value of those exports increased from $600 million in 1996 to $1.8 billion in 2010. Traditional Chinese medicines include proprietary Chinese medicines, raw materials and ingredients, as well as herbal extracts.

- **Biological Industry Development Plan (China Daily, 2012-02-14) – February 14, 2012**
  Discussion by professionals on China's 12th Five-Year Development Plan (2011-15) with regard to the biological industry was completed by an expert consultative committee, paving the way for the plan to be submitted to the State Council for approval, according to the National Development and Reform Commission (NDRC). In line with the plan, China's biological industry development is to focus on five sectors – bio-pharmaceuticals, bio-agriculture, bio-energy, biological environment protection, and biological service outsourcing – during the 12th Five-Year Development Plan period. The value of the nation's biological industry is expected to reach 4 trillion yuan ($635 billion) by 2015 and between 8 trillion yuan and 10 trillion yuan by 2020. The plan also prioritizes local development of genetic engineering.

- **State Council Arranges Medical Reform Work during 12th Five-Year Period (www.ce.cn, 2012-02-23) – February 23, 2012**
  Premier Wen chaired an executive meeting on February 22 to arrange the medical reform work during the 12th Five-Year Period. Premier Wen pointed out that the medical reform has progressed significantly as of 2009: the basic medical insurance system covering rural and urban residents, the national essential drug system and the basic medical treatment and health service system have been established; the average public health service level has been significantly improved; and the reform of public hospitals is underway. China will focus on the following three aspects to deepen its medical reform during the 12th Five-Year Period:

  (i) To expand the nationwide coverage of the medical insurance system. The average medical insurance for urban residents and government subsidy for rural residents will exceed RMB 360/year/person. By 2015, 75 percent of the hospitalization expenses will be reimbursed.

  (ii) To improve the national essential drug system and the management of the local level medical institutions. More than 150,000 doctors will be assigned to local-level medical institutions.

  (iii) To promote the reform of public hospitals. The common practice of increasing hospital revenue by excessive prescriptions will be restricted.

  The meeting also lowers the thresholds for social capital to enter into the medical industry. The competent enterprises, charity institutions, foundations, commercial insurance institutions, and foreign enterprises are encouraged to establish medical institutions, and qualified medical practitioners are encouraged to open private clinics.

- **Chinese Vaccine Companies Going Global (Xinhua News Agency, 2012-02-29) – February 29, 2012**
  One year from the World Health Organization's (WHO) freeing Chinese vaccine producers to apply for rights to distribute their products globally, none have qualified to do so, Health News, the newspaper affiliated with China's health ministry, reported. The paper noted that Chinese vaccine companies are still a ways from going global. On March 1, 2011, China's national regulatory authorities, represented by the State Food and Drug Administration, in the area of vaccines were accredited by the WHO as "functional," after failing three previous tests in 1999, 2001 and 2005. The recognition enabled Chinese manufacturers to apply to have their vaccines "pre-qualified" by the WHO, an accreditation which would mean the products could be supplied through United Nations agencies to developing countries. However, at present, only the Henan-based Hualan Biological Bacterin Co. Ltd, and the Chengdu subsidiary of China National Biotec Group have submitted applications for this "WHO license" – for their seasonal flu vaccine and Japanese encephalitis vaccine, respectively. They have not yet won approval.

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