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China Life Sciences and Health Industry Client Briefing – August 2012 (September 18, 2012)

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

News

Notice from the Ministry of Health Concerning Hospital Procurement of Class-A Large-Scale Medical Equipment – August 16, 2012 The Ministry of Health issued regulations August 7, 2012, to regulate the collective procurement of Class-A, large-scale medical equipment. The equipment in the Regulations refers to the large-scale medical equipment under the classification of Class A. The nonprofit medical institutions set up by the government at all levels, and state-owned or controlled enterprises, shall participate in the collective procurement. The collective procurement shall be carried out through the following methods: (i) public bidding; (ii) invitation to tender; (iii) competitive negotiation; (iv) single-source procurement; (v) inquiry; and (vi) other methods prescribed in relevant regulations. The regulations also clarify the rules on management, procurement parties, selection of the bidding agent, and expert management, among others.

MOH to Investigate Infection Events in Hospitals Due to Inadequate Prevention and Control System (Beijing Youth Daily 2012-08-05) – August 5, 2012 The Ministry of Health (MOH) issued a notice to strengthen the supervision of key hospital departments, including the sterilization and supply center, the intensive care unit, the operating room, the neonatal room, the hemodialysis room, and the burn ward. The medical institutions are required to strictly abide by technical standards regarding infection control. The medical institutions shall keep clean and disinfected any medical supplies in close contact with patients. Any serious infection events will be subject to investigation, and the responsible hospital personnel may be held accountable.

Wenzhou Plans to Attract Private Medical Investors (China Daily 2012-08-08) – August 8, 2012 Municipal government officials in Wenzhou, Zhejiang province have developed new plans that could establish the city as the private medical capital of China. The city

– long-renowned for its large population of entrepreneurs – has received opinions from central government on a draft plan that could call for offering incentive policies on land use, taxation and favorable investment return for investors. A local Wenzhou government source confirmed to *China Daily*: “The central government has provided suggestions to us, and we are doing revisions,” but declined to disclose further details. According to a report appearing in *21st Century Business Herald* on Monday, August 6, the plan’s incentives could make hospital investors exempt from property tax and land-use fees during the first three years of operation. According to officials, the municipal government is proposing that it provide funds of at least 20 million yuan (\$3.14 million) annually to support private hospitals, and interest-free loans will be offered for larger projects.

Notice Concerning Public Hospital Reform in 2012 – August 8, 2012 The Ministry of Health (MOH) issued the notice to clarify several issues in the reform of public hospitals in 2012. The pilot cities are required to phase out the subsidizing of medical services with drug sales revenues, based on drug price mark-ups. The public hospitals may increase the revenue from service fees and financial subsidies, but not drug price mark-ups any more. A modern hospital management system shall be established in the public hospitals. The management system of hospital directors’ qualifications, and the responsibility system and assessment system, will be established and improved. MOH will vigorously promote the comprehensive reform of county-level hospitals and expand the measures and policies nationwide. Furthermore, the private medical institutions will be further encouraged. The local health authorities are required to formulate detailed rules for private medical institutions and to advance the preferential policies with regard to pricing, taxation, medical insurance of designated hospitals, land, key science project construction, and post-evaluation on professionals.

MOH to Establish EDLs for Secondary and Tertiary Hospitals (Shanghai Securities News 2012-08-28) The PRC Ministry of Health (MOH) indicated recently that it aims to expand the basic drug system (essential drug list - EDL) to secondary and tertiary hospitals. MOH official Wang Xuetao noted that the primary health sector should be equipped with essential drugs, and that implementation efforts need to be strengthened. Currently, more than 10 provinces – including Zhejiang and Anhui – have instituted basic drug use initiatives in their secondary and tertiary hospitals. For these provinces’ secondary hospitals, sales from essential drugs will need to reach 25 percent to 35 percent of total drug sales. Tertiary hospitals will need essential drug sales to attain 15 percent to 25 percent portion of total sales.

Pricing Developments for Drugs of Foreign Companies (China Youth Daily 2012-08-13) – August 13, 2012 Lowering drug prices is one of the government’s priorities to reduce expensive medical services and products for Chinese citizens. In the past 14 years, the National Development and Reform Commission (NDRC) has decreased drug prices 29 times. However, the government did not extend price reductions to some brand drugs during the price adjustments. In many countries, a newly developed drug may enjoy a 20-year patent protection. Other companies will develop and market similar drugs after the patent protection period expires. However, in China, such brand drugs may have beneficial pricing even after the patent protection has expired. In the early 1990s, China’s patent law didn’t recognize the patent rights of drugs of international pharmaceutical companies

entering the Chinese market, so these companies kept requesting that the government protect the original drug pricing. One response was for the Chinese government to allow continued prices of originally marketed brand drugs without being subject to price reductions. NDRC has gradually narrowed the price difference between the original brand drugs and generic drugs, and issued a draft Administrative Measures on Drug Prices in 2010 that suggests eliminating the price differences between original brand and generic drugs. However, the Measures have not been finalized or issued, and there does not appear to be any particular deadline.

MOH Plans to Issue Regulations on Criminal Prosecutions for Leak of Confidential Patient Information on Tuberculosis (Beijing Morning Post 2012-08-09) – August 9, 2012 The Ministry of Health (MOH) released the revised Administrative Measures on Prevention and Treatment of Tuberculosis for comments. According to the draft, the health administration may collect information from entities and individuals if necessary for tuberculosis monitoring and control. However, the health administration and its officials shall keep patients' privacy confidential. Administrative punishment and even criminal liability shall be considered for the personnel who leak patients' personal information. The designated tuberculosis medical institutions are required to carry out registration management on tuberculosis patients, and emergency-response measures shall be initiated when the tuberculosis epidemic constitutes a public health emergency.

One-Month Trial Operation of The University of Hong Kong-Shenzhen Hospital with Complaint Rate of 0.8% (Caixin Media 2012-08-14) – August 14, 2012 The University of Hong Kong-Shenzhen Hospital is the first public hospital under the "pilot" program in the Hong Kong-Guangdong Cooperation, which has run for more than one month. During this period, it received only 0.8 percent complaints from more than 7000 patients. The pilot operation started from this July to this September. The hospital cancels the traditional staffing mechanism and recruits all staffs by contract. General out-patient services are introduced by the hospital, which includes 26 examination projects and drugs for seven days and only charges RMB 130. The hospital will keep the charge unchanged for one year. According to the statistics of the hospital, it will provide 300 out-patient services every day, and 97.7 percent of the services are through appointments during the pilot operation. The hospital is expected to add five departments, including ENT, ophthalmology, etc., this October, and to open an emergency department next June.

MOH Strictly Controls Establishment of Medical Institutions (Caixin Media 2012-08-14) – August 15, 2012 On August 13, the Ministry of Health (MOH) promulgated the Notice concerning Strengthening Approval and Verification of Establishment of Medical Institutions, stressing the administrative functions of local health authorities. The local authorities are required to carefully identify the classes, categories and diagnosis subjects of medical institutions, and carry out periodic supervision and examination of the medical institutions in their jurisdictions. Any medical institutions that do not meet relevant requirements shall not be approved. The move aims to address the proliferation of "black clinics." However, a number of private practice doctors consider that the current administrative approval system does not ensure the quality of medical services. The "black clinics" widely exist and a variety of policy barriers keep doctors who intend to carry out independent practices away from opening private clinics. Some experts suggest the health

authorities shall enhance the supervision, rather than the administrative controls to solve the problem.

MOH Questions Validity of Appraisals of 240 A-Class Hospitals (Caijing 2012-08-27) – August 27, 2012 Recently, the Ministry of Health (MOH) required the local health agencies to re-appraise the A-Class hospitals approved since 2011. Around 240 hospitals that were approved as A-Class hospitals since 2011 are considered underqualified, and their approval certificates and the grade identifications will be revoked. An official from MOH said around half of these hospitals are county-level hospitals. Some A-Class county-level hospitals only cover 100,000 people, while some are township health centers, which cannot meet standards for A-Class hospitals. The current situation may undermine the entire health care service network. MOH asked the local counterparts to report any appraisal results of 1st grade A-Class hospitals and newly approved A-Class hospitals, and will make the final approvals accordingly.

Medical Device Producer Announces M&A Plans (China Daily 2012-08-11) – August 13, 2012 Medtronic, Inc. plans to bolster its presence in China via mergers and acquisitions of local companies, becoming another major multinational medical equipment provider to announce such a strategy in the world's fastest-growing medical device market. Simon Li, vice-president of the U.S.-based company and president of Medtronic Greater China, said that the medical device producer already has some candidates and is still looking for others.

U.S. SEC Charges Drug Company with Foreign Bribery (Xinhua News Agency 2012-08-08) – August 8, 2012 The U.S. Securities and Exchange Commission (SEC) on Tuesday, August 7, charged Pfizer Inc., a major U.S. pharmaceutical firm, with violating the Foreign Corrupt Practices Act (FCPA), as its subsidiaries are allegedly involved in improper practices to obtain business in foreign countries. The SEC alleged that employees and agents of Pfizer's subsidiaries in Bulgaria, China, Croatia, the Czech Republic, Italy, Kazakhstan, Russia, and Serbia made improper payments to foreign officials to obtain regulatory and formulary approvals, sales, and increased prescriptions for the company's pharmaceutical products. Pfizer's actions dated back to 2001, according to the regulator's complaint.

State Council to Release Regulation Permitting Local Governments to Buy Commercial Insurance for Serious Illnesses (Xinhua News Agency 2012-08-21) The State Council Health Care Reform Office and PRC agencies will jointly release the Guiding Opinion on Insurance for Serious Illnesses for Urban and Rural Habitants at the end of August, according to Shanghai Securities News August 21. The regulation states that local governments may purchase commercial insurance for serious illnesses through basic health care funds, although percentages of the premiums may vary from locality to locality. Chinese companies that currently have pilot programs on commercial insurance in place include PICC Health Insurance and Pacific Life.