

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

**Jay J. Yan**  
Partner, Shanghai  
+86 (21) 6032 3166  
jyan@reedsmith.com

**Mao Rong**  
Counsel, Beijing  
+86 10 6535 9500  
mrong@reedsmith.com

**May Wong**  
Associate, Hong Kong  
+852 2507 9702  
mwong@reedsmith.com

**Amy Yin**  
Associate, Shanghai  
+85 (21) 6032 3108  
ayin@reedsmith.com

**John J. Tan**  
Counsel, Shanghai  
+86 (0)21 6032 3126  
jtan@reedsmith.com

**Katherine Yang**  
Associate, Beijing  
+86 10 6536 9542  
kyang@reedsmith.com

**Vicki Lung**  
Associate, Washington, D.C.  
+1 202 414 9281  
vlung@reedsmith.com

**Gordon B. Schatz**  
Partner, Shanghai/  
Washington, D.C.  
China: +86 1350 109 1380  
D.C.: +1 202 414 9259  
gschatz@reedsmith.com

...or the Reed Smith lawyer with whom you regularly work.

## China Life Sciences Health Industry Client Briefing – January 2013 (February 21, 2013)

### Pharmaceuticals, Medical Devices, Health Care & Life Sciences News & Regulations

- **Li Keqiang Comments from the 12th Plenary Meeting of the Medical Reform Leading Group (USCBC 2012-01-06) – January 6, 2013** On January 5, Li Keqiang, the Vice Premier and Deputy Secretary of the State Council, chaired a meeting of the State Council Medical Reform Leading Group. During this meeting, Li reported that reforms are necessary to address the disparity in healthcare development between rural and urban areas. To address this gap, reforms will begin by improving basic health security, strengthening grass roots' capabilities, and focusing on rural areas and the central and western areas of China. Li noted that any reforms that are implemented must rely closely on a system that is based on innovation, which requires both an increased investment from the financial sector as well as an environment to facilitate such innovation. Instead of relying on pharmaceutical drug sales as a significant source of income, Li suggested that the medical system in China should instead focus its efforts on improving insurance coverage for major diseases and providing medical emergency aid. Finally, Li advocated the promotion and expansion of pilot reforms for public hospitals.
- **MOH Announces Roadmap for Medical Reform (USCBC 2012-01-10) – January 10, 2013** On January 7, the Ministry of Health (MOH) released the Roadmap for Medical and Healthcare Reform at the 2013 National Health Conference. The eight-point roadmap included key highlights such as:
  - Improving the new rural cooperative medical-care system
  - Reinforcing and advancing the national essential drug system

- Enhancing the level and efficiency of primary health care services
- Actively promoting the reform of public hospitals to safeguard public welfare

At the conference, the Minister of Health, Chen Zhu, cautioned that for 2013, more than 50 percent of all Chinese county-level hospitals must stop relying on pharmaceutical drug sales as a major source of income. In addition, reforms will be enacted to improve social capital investment. Specifically, reforms will focus on promoting the development of private medical institutions, with the expectation that non-public medical institutions will provide 20 percent of total hospital beds and medical services by 2015. The latest data from the MOH shows that in 2012, the central government invested a total of RMB 24.3 billion (US\$3.9 billion) to improve construction for China's medical- and health-services system. In 2012, the new rural cooperative medical coverage exceeded 95 percent and RMB 290.00 (US\$46.6) per capita funding.

- **MOH Highlights Local Medical Reforms (Caijing 2013-01-16) – January 17, 2013** The MOH presented examples of medical reforms that have been implemented at provincial or municipal levels, including the following:
  1. *Optimization of medical resources to rural areas* – Supported by government funds, Shanghai implemented the “5+3+1” medical service system: “5” refers to the introduction of high-quality medical resources to five suburb districts; “3” refers to the upgrade of central hospitals located in three rural and remote districts to the A-class level; and “1” refers to the relocation of one hospital to Jinshan district in order to support the southwestern population in Shanghai and neighboring areas.
  2. *Comprehensive training for medical professionals* – Tianjin established 143 general-practitioner and resident-physician training bases covering 18 medical disciplines.
  3. *Payment method reform in rural areas* – Henan Yiyang county initiated a comprehensive payment system for patients living in rural areas. A fixed charge system will apply for patients with ordinary and/or serious medical conditions, whereas a pro rata reimbursement system, based on actual expenses, will apply for patients with more severe medical conditions.
  4. *Hospital revenue growth no longer relies on price mark-ups for drugs and excessive sales* – In Beijing, certain hospitals initiated pilot programs to restructure the revenues associated with “drug prescribing” from those considered to be “medical services.” In doing so, the profit originally gained from the sales of drugs with significant mark-ups, would be lowered, and revenues focused instead coming from registration fees and

consultation fees. Fees for drugs would become part of medical service fees that are charged based on the seniority of the doctors.

5. *More transparent drug bidding and tendering process* – With the goals of drug quality and reasonable prices in mind, the province of Anhui implemented a unified, online centralized-bidding system for drugs contained in the unified drug bidding catalog and the essential drug catalog.
  6. *Medical expense control* – The province of Zhejiang established improved control systems within hospitals to help manage costs from medical expenses and medical insurance.
  7. *Expanded social security system for doctors working in rural areas* – The province of Jiangsu expanded its urban employee pension-insurance to cover doctors working in rural areas. The Jiangsu government also provided them with certain financial subsidies.
  8. *Medical coverage for severe diseases* – To align with the requirements set forth by the MOH, the province of Jiangxi completed the medical coverage of 21 severe diseases. Additionally, the province implemented free treatment for six major diseases, including cataracts, cleft lip and palate, and childhood leukemia.
  9. *Combination and cooperation of medical institution to span across province* – The province of Henan established a medical association to carry out, among other things, training, free clinics and health talks, within institutions spanning four districts and one county. This initiative is headed by Zhengzhou Central Hospital.
- **More Cities in Jiangsu to Pilot Public Hospital Reform Program (USCBC 2012-01-06) – January 6, 2013** According to the Jiangsu Provincial Price Bureau, plans were approved, at the end of 2012, that will enact comprehensive reforms of pharmaceutical drug prices in the cities of Zhenjiang, Yixing, Rugao, and Dongtai. One of the requirements set forth by the Provincial Price Bureau mandates that the price of drugs sold to patients at public hospitals participating in the pilot program must be reduced by 15 percent.
  - **MOH to Release New National Essential-Medicine List Soon (USCBC 2012-01-04) – January 5, 2013** On December 26, at a press conference to announce China's medical and health services white paper, Zhang Mao, the Deputy Minister of the MOH, stated that the publication of a revised national essential-medicines list is forthcoming. The new list will be implemented in basic medical and health institutions. Zhang also stated that, following the release of the essential-medicines list, the MOH plans to issue new policies

that will encourage all medical and health institutions in China to give priority to such essential medicines. The current version of the national essential-medicines list includes 307 medicines.

- **Price Cut for 20 Types of Drugs (China Daily 2013-01-09) – January 9, 2013** According to an official at the offices of the country's top price regulator, China will adopt new methods, including comparisons of international drug prices, to help regulate the price of imported drugs. As part of efforts that have been ongoing since 2011, five price adjustments have initiated and facilitated large-scale drops in the prices for imported medicines. Song Dacai, Director of the Medicine Pricing Section of the National Development and Reform Commission (NDRC), the country's top economic planning body, indicated that in 2013, Chinese herbal medicine will be the next target for price adjustments, as well as high-priced drugs with high-profit margins. The new methods adopted by China will also adjust drug prices in accordance with changes in manufacturing costs. Song explained that imported drugs will most likely be priced using international price comparisons. Starting February 1, NDRC will cut the maximum retail prices of about 400 drugs in 20 categories—including medicines used to treat respiratory diseases and fever—by an average of 15 percent.
- **Only 597 Drug Manufacturers Have Obtained New GMP Certification by the End of 2012 (USCBC 2013-01-09) – January 9, 2013** According to the State Food and Drug Administration (SFDA), only 597 out of 4,669 Chinese drug manufacturers had obtained the new good manufacturing practice (GMP) certification by the end of 2012. In response, the SFDA recently released a circular stating that manufacturers of axenic drugs, including those producing injections, must complete the new GMP certification process before January 1, 2014. Other drug manufacturers must achieve GMP certification before January 1, 2016, or risk suspension of production efforts.
- **China Orders Chemical Pharmaceutical Exports Survey (Xinhua News Agency 2013-01-19) – January 21, 2013** China's drug safety watchdog, "Friday," ordered a survey of the active pharmaceutical ingredients (API) exported by the country's chemical pharmaceutical manufacturers. The SFDA said that the manufacturers must report the names, license numbers, and major export destinations of their API, as well as whether they possess a European certificate for good manufacturing practices.
- **Output Value of Yunnan's Biological Industry to Exceed RMB 1.2 Trillion (US\$193.1 billion) by 2020 (USCBC 2012-01-10) – January 10, 2013** According to a provincial conference on biological industry development conducted on January 9, the government of Yunnan province plans to boost the development of six bio-related industries as part of its efforts to promote

provincial transformation and upgrade of the biological industry. Specifically, the affected biological industry includes bio-agriculture, bio-forestry, bio-medicine, bio-energy, biological manufacturing, and biological environmental protection. The conference concluded that the total expected output value of the province's biological industry will exceed RMB 800 billion (US\$128 billion) and RMB 1.2 trillion (US\$193.1 billion) by 2016 and 2020, respectively.

- Biopharma Firms Boosted by Policy Support (Global Times 2013-01-08) – January 8, 2013** Following the announcement of plans to develop the domestic biotech industry, with a focus on enhancing the competitiveness of the biomedical sector in the global market, biopharmaceutical firms saw their shares rise in the mainland stock market. Shares in 14 biopharmaceutical firms, such as Beijing Tiantan Biological Products Co. and Henan-based Hualan Biological Engineering, climbed by the daily limit of 10 percent in the Shanghai and Shenzhen stock markets. According to the plan unveiled by the State Council, between 2013 and 2015, China's biomedical industry will see an annual growth rate of more than 20 percent.
- Health Insurance to Cover 95% of Rural Residents (China Daily 2013-01-08) – January 8, 2013** Chen Zhu, the Minister of Health, indicated that China will increase spending on public health insurance, particularly for rural residents, to ensure that at least 95 percent of its rural population is covered. At a national conference on health work, Chen explained that under a new cooperative medical care system designed exclusively for rural people, the government subsidy is expected to reach 280 yuan (US\$45) per person annually in 2013, up from the current 240 yuan.
- Actis Invests in Nanjing Medical Equipment Producer (China Daily 2013-01-09) – January 10, 2013** Actis Capital LLP, a global private equity firm, announced that it had made a minority investment in Micro-Tech (Nanjing) Co. Ltd, a specialist medical equipment manufacturer. Although the amount of the investment was not revealed, the investment marks a sign of confidence in the Chinese healthcare industry.
- Stryker to Buy Firm to Expand in China (Shanghai Daily 2013-01-18) – January 18, 2013** Stryker Corp., a Michigan-based manufacturer of specialty surgical and medical products, has offered to buy Trauson Holdings Co. for US\$764 million in cash as part of its expansion efforts in the Chinese orthopedic market. Trauson is China's largest maker of pelvic reconstruction plates and other products used in trauma surgery. "The acquisition of Trauson is a critical step toward broadening our presence in China and developing a value segment platform for the emerging markets through a well-established brand," Stryker CEO Kevin A. Lobo said in a statement. Stryker and Trauson have had a relationship under a manufacturing agreement for instrumentation

sets since 2007. According to Frost & Sullivan, a market research firm, it is expected that, following the acquisition, orthopedic implant sales in China will almost double to US\$2.7 billion by 2015, vaulting the country past Japan as the biggest market after the United States.

- **China to Speed up TCM Standardization (Xinhua News Agency 2013-01-11) – January 11, 2013** In order to promote the use of traditional Chinese medicine (TCM) overseas, China will accelerate the establishment and revision of TCM standards. At a national TCM work conference, Wang Guoqiang, Vice Minister of Health and Director of the State Administration of TCM, explained that the standardization of TCM will not only enhance the development of TCM, but will also guarantee its quality. Official statistics indicate that the central government spent 3.34 billion yuan (US\$534.5 million) to support TCM development last year.
- **Q&A re Adjustment of Occupational Disease Classification and Catalogue (Ministry of Health 2013-01-18) – January 22, 2013** Recently, the MOH issued a draft of the new Occupational Disease Classification and Catalogue for public comment. Several changes were made, including the addition of 17 diseases, deletion of one disease, and readjustment of the names of 16 diseases. The new draft of the catalogue now includes 130 occupational diseases. The occupational diseases are still classified into 10 categories, including, among others, occupational lung and other respiratory diseases, occupational skin diseases, occupational ophthalmopathy, occupational ear, nose and throat (ENT) and oral diseases, occupational chemical poisoning and other diseases caused by physical factors, the occupational radiation diseases, occupational infectious diseases, and occupational cancer.