

China Life Sciences and Health Care Industry Alert

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CHINA BRIEFING January 2012 (February 13, 2012)

Pharmaceuticals, Devices, Health Care & Life Sciences

Regulations

- **Notice from the Ministry of Health concerning the Outline of China's Nursing Development Plan from 2011 to 2015 – January 9, 2012**

On December 31, 2011, the Ministry of Health issued the Outline of China's Nursing Development Plan (2011 – 2015), which clarifies the goals in developing nursing services during the 11th five-year period. The Outline presents the guiding ideologies and principles, main goals and key tasks of development, major development projects, and safeguard measures from 2011 to 2015. By 2015, the number of registered nurses should reach 2.86 million, of which 300,000 will be located in primary medical institutions. In addition, China will select 10 cities for a long-term nursing services pilot program.

- **Promulgation of Eight Recommended Medical Product Industry Standards – January 9, 2012**

On December 14, 2011, the Ministry of Health (MOH) released an announcement to establish eight medical product industry standards that include:

- Enzymatic determination of serum triglycerides
- Interoperability matrix effects and evaluation guidelines
- Clinical application guidelines of markers of bone metabolism
- Immunoassay of serum (plasma) lipoprotein (a)
- Collection and handling guidelines of blood specimen for coagulase tests
- Guidelines for flow cytometry in peripheral blood lymphocyte subsets
- Reference methods of determination of catalytic activity concentrations of lactate dehydrogenase
- Spectrophotometry of serum cholesterol reference measurement procedures

The new standards will come into force June 1, 2012.

- **Notice concerning Strengthening Implementation of 2010 GMP Amendment – January 18, 2012**

On January 6, 2012, the State Food and Drug Administration issued a notice to strengthen the implementation of the newly revised Good Manufacturing Practices (GMPs). The notice requires local companies to formulate an overall implementing plan, which will include the formation of teams to improve supervision. The notice also requires pharmaceutical enterprises to improve the quality management system and give priority to technical upgrading.

- **Notice concerning Circulation of the 12th Five-Year Plan for Medical Device Technology Industry**

The Ministry of Science and Technology formulated the plan to support the development of the medical device technology industry. The plan comprises six parts, namely, background and demand, guiding principles, development goals, development priorities, key tasks, and safeguard measures. China will give priority to supporting 10 to 15 large-scale medical devices groups and 40 to 50 creative high-tech enterprises, and to

establishing eight to 10 medical device technology bases and 10 national creative medical device products demonstration bases.

News

- **UK Drug Maker Builds Factory in Jiangsu (Shanghai Daily 2012-01-04) – January 5, 2012**
AstraZeneca today started construction on a US\$230 million plant in Jiangsu Province (near Shanghai) as it expands with other multinational drug companies to ride on the growth of China and other emerging markets. The new manufacturing facility – the largest of AstraZeneca's facilities – is expected to be completed at the end of 2013.
- **Minister of Health: Hospital Mark-ups for drug sales to patients to be ended. Pilot Program in 300 Counties (Caijing 2012-01-06) – January 6, 2012**
On January 5, Chen Zhu, Minister of Health, stated that the hospitals would no longer be allowed to profit from the significant mark-ups of drug prices sold to patients. This will be done during the 12th five-year plan period. The mark-up pricing for drugs led to unreasonable increases in medical costs and other abuses, including improper prescribing practices by medical staff. This year, MOH will launch a pilot project in 300 counties to address the changes in hospital revenue. Hospitals at county level will roll out the pilot project in 2013. All the public hospitals will be covered by 2015.
- **Expansion of partnership between Bristol Myers Squibb and Simcere (China Daily 2012-01-09) – January 9, 2012**
Pharmaceutical company Bristol-Myers Squibb Co (BMS) and the Jiangsu-based Simcere Pharmaceutical Group expanded their strategic partnership to co-develop an oncology compound (the creation and development of a cancer treatment). Recently, and with research and development (R&D) into the compound still at an early stage, BMS announced that it will expand the strategic partnership to explore broader indications, such as for cardiovascular diseases.
- **Fosun Plans HK IPO (Global Times 2012-01-09) – January 9, 2012**
A \$600 million to \$800 million initial public offering (IPO) by China's Fosun Pharmaceutical is set to hit the Hong Kong market in March, Reuters reported. The Shanghai-listed company, one of the subsidiaries of Fosun International, plans to sell not more than 20 percent of its expanded share capital for the Hong Kong IPO.
- **China Drafting Traditional Chinese Medicine Law (China Legal Information Center 2012-01-12) – January 12, 2012**
Currently, the Ministry of Health and the State Administration of Traditional Chinese Medicine are drafting a traditional Chinese medicine law. The law has been listed in the 11th NPC legislation plan. The two authorities will speed up the drafting work and submit a draft to NPC for review as soon as possible.
- **Beijing to Establish 21 Large-Scale Hospitals Around the Fifth Ring Road (Caixin Media 2012-01-17) – January 18, 2012**
According to the fifth meeting of the 13th Beijing People's Congress, Beijing will not establish large-scale hospitals within the fourth ring road. In the future, Beijing will upgrade 21 qualified hospitals to the third level around the fifth ring road area and form a "high-quality medical resource belt" by 2015. Beijing also encourages investors to set up hospitals in rural areas and new urban areas.
- **Pharma and Medical Exports Likely to Surge (China Daily 2012-01-18) – January 18, 2012**
The growth of imports and exports of Chinese-made medicines and health products almost doubled the growth rate of the nation's total foreign trading volume as a whole during the first 11 months of 2011, and is expected to continue increasing this year. Meanwhile, Chinese exports of pharmaceuticals and medical equipment to emerging markets such as India, Brazil, and Russia witnessed a surge over the same period. The increase suggests that Chinese enterprises are diversifying their export destinations to avoid trading barriers in developed markets, according to the China Chamber of Commerce for Imports & Exports of Medicine and Health Products.

- 12th Five-Year Plan on Medical Device Technology Issued: RMB 200 Billion to be Contributed to Output Value (China Securities Journal 2012-01-19) – January 19, 2012**

On January 18, the Ministry of Science and Technology issued the 12th Five-Year Plan on the Medical Device Technology Industry, clarifying key products, major industrial layout, and safeguard measures. The output value of medical devices during the 12th five-year period is expected to increase by RMB 200 billion. Eight to 10 large-scale medical device groups whose output values exceed RMB 5 billion will be formed.
- Medical Insurance Reform (China Daily 2012-01-19) – January 20, 2012**

Reform of public welfare programs signals major changes in what previously has been free health care enjoyed by civil servants. Under consideration are ways to incorporate public health and welfare programs into the general employees' medical insurance system. The medical costs of all 450,000 of the civil servants in the Beijing municipal government and its affiliated county and district governments have already been merged into employees' medical insurance since January 1, and the change will be extended to civil servants in the central government next year. The move shows the authority's determination to extend reform at the national level and certain municipalities, and will encourage more local authorities at various levels to follow its lead.

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