ReedSmith

Client Briefing – China

Life Sciences Health Industry

China Life Sciences Health Industry Client Briefing – May/June 2013 (July 12, 2013)

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

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

Amy Yin
Associate, Shanghai
+86 (21) 6032 3108
ayin@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

Jay J. Yan
Partner, Shanghai
+86 10 6535 9542
jyan@reedsmith.com

John J. Tan
Counsel, Shanghai
+86 (21) 6032 3188
jtan@reedsmith.com

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

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

Pharmaceuticals, Medical Devices, Health Care & Life Sciences

Medical Devices

Regulations and News

Provincial FDAs to Approve Certain Changes to Medical Device Registration Certificates – June 21, 2013 In late June, the China Food and Drug Administration ("CFDA") issued a notice delegating some approval and inspection duties to China's provincial-level FDA agencies. First, as of October 1, 2013, FDAs at the provincial level have the responsibility for approving certain changes to the registration certificates of Class III medical devices and Class III in vitro diagnostic reagents, such as changes to the names and addresses of companies. Second, as of July 1, 2013, FDAs at the provincial level will also have the authority to handle the quality management system inspection for certain medical devices and Class III in vitro diagnostic reagents as well.

CFDA Issues Acceptance Standards for Distributors of In Vitro Diagnostic Reagents (Medical Device) – May 16, 2013 In May, the CFDA issued a notice clarifying the detailed requirements for distribution enterprises of in vitro diagnostic reagents (medical devices). The notice, which spans 14 articles, sets forth various requirements for distribution enterprises relating to, among other things, organization and staff, system and management, and facilities and equipment. Specifically, the notice provides requirements for the size of, and type of building allowable for, the business place of such distribution enterprises. The notice also stipulates that quality management personnel may not take other positions within the enterprise. Moreover, distribution enterprises shall establish internal management systems, including quality management and responsibility

systems, as well as work procedures.

CFDA Solicits Public Comments on the Catalogue of Class II Medical Devices Exempted from Requirement for Clinical Test Materials (Second Batch) – May 22, 2013 From late May through the end of June, the CFDA solicited public comment regarding a draft of the Catalogue of Class II medical devices, for which clinical test materials are exempted from product registration. The draft Catalogue contains 142 medical devices, including, among.

Drugs

Regulations and News

China Tightens Supervision Over Drug Advertising (Xinhua News Agency 2013-06-21) – June 24, 2013 In an effort to reduce scams associated with drug ads, publishing units have been ordered to tighten supervisory efforts over advertisements for drugs and health care products. Publications should neither advertise drugs or health care products, nor recommend such products to doctors or medical care institutions in the form of a scientific knowledge lectures or expert consultations. Advertisements disguised as other forms, such as news reports, should also be banned from publication.

Major International Drug Firm is Investigated in China (*New York Times* 2013-07-01) – July 2, 2013 The British pharmaceutical giant, GlaxoSmithKline recently noted that Chinese authorities are investigating whether senior managers were involved in questionable practices while working for the company in China. A spokesman in London said that GlaxoSmithKline was unaware of the specifics of the investigation, but that the company's executives have been cooperating. The public security bureau in the city of Changsha, in central China's Hunan province, posted a brief statement online announcing the investigation. The Chinese police also detained GlaxoSmithKline managers in Shanghai, Beijing and Changsha, according to a recent edition of *The South China Morning Post*.

CFDA Issues Notice on Implementation of New GSP Standards – June 24, 2013 In late June, the CFDA issued a notice requiring the implementation of the new Good Supply Practice for Pharmaceutical Products ("GSP") standards by FDAs at the provincial level by the end of 2015. The notice provides for the following implementation timetable:

- Effective as of the date of the notice, FDAs at provincial levels must follow the new GSP requirements during the review and approval processes for the renewal of drug distribution permits or GSP certification for existing drug distributors, including both wholesaler and retail distributors. If a drug distributor, seeking renewal of GSP certification, fails to meet the new GSP requirements by December 31, 2013, a grace period of six months may be granted.

- By July 1, 2013, drug distribution permits and GSP certification may only be approved if the premises of newly established and existing drug distributors are compliant with the new GSP requirements.
- By December 31, 2014, wholesalers: (i) engaged in the business of distributing vaccine, narcotic drugs, psychotropic drugs, protein assimilation preparation and peptide hormone, or (ii) permitted to accept the entrusted storage and delivery of such drugs, must be compliant with the new GSP requirements, or face the possibility of license revocation.
- By December 31, 2015, all drug distributors must meet the new GSP requirements, regardless of whether their drug distribution permits or GSP certification has expired. Distributors failing to do so will be prohibited from drug distribution activities beginning in 2016.

Zhejiang Beta Pharma and Amgen Form Joint Venture (Xinhua News Agency 2013-05-10) – May 13, 2013 Zhejiang Beta Pharma Co., Ltd. ("Zhejiang Beta Pharma") and Amgen, Inc. ("Amgen") announced the formation of a joint venture to commercialize Amgen's anti-cancer prescription medication in the Chinese market. Zhejiang Beta Pharma and Amgen will own 51 percent and 49 percent of the new venture, respectively. Although still subject to approval by relevant government authorities in China, the joint venture will be named Amgen-Beta Pharmaceuticals Co., Ltd. Zhejiang Beta Pharma has leading expertise in molecularly targeted therapies and oncology treatment products in China. Amgen, a U.S.-based biopharmaceutical company, has global expertise in the development and manufacture of human therapeutics.

Shanghai's Biopharmaceutical Sector is a Star in Slow Economy (*Shanghai Daily* 2013-05-15) – May 15, 2013 For four years in a row, Shanghai's biopharmaceutical industry's output has risen by 15 percent annually. In 2012, the industry achieved 208.48 billion yuan (US$33.9 billion) in output, making it one of the few industries to expand by double digits despite the city's slow economic growth. According to local officials at a briefing about the industry's development, boosting biopharmaceutical development not only benefits the city's economy, but also helps to cut health care costs because home-grown products and medicines cost less than imported ones. Shanghai will continue to support the industry under a new four-year plan starting this year.

Chinese Pharma Companies Look West (*China Daily* 2013-05-20) – May 20, 2013 Recent collaborations between Chinese pharmaceutical companies and multinational pharmaceutical manufacturers have enabled Chinese manufacturers to access international markets, to implement technical product and manufacturing upgrades, and to gain brand recognition through the global platforms of foreign pharmaceutical partners. Multinational pharmaceutical companies also benefit from such collaborations by leveraging Chinese

distribution networks and local knowledge to expand their market share in China. Some recent collaborations include:

- A joint venture formed in September 2012 between state-owned Zhejiang Hisun Pharmaceutical Co. and U.S.-based Pfizer, Inc.
- Partnerships between Simcere Pharmaceutical Group and Merck & Co. and Bristol-Myers Squibb Co.
- A distribution agreement between Chinese biotech company Sino Biological Inc. and Life Technologies Corp. for the distribution and development of Sino Biological's proteomics products worldwide
- Investments by Shanghai Fosun Pharmaceutical (Group) Co., Ltd. in U.S.-based medical care company Saladax Biomedical Inc., enabling it to become the largest single shareholder

Drug Distributors 'Need to Consolidate' (*China Daily* 2013-05-20) – May 20, 2013 According to a report by international services firm KPMG, in light of the current fragmentation of China's pharmaceutical market, as well as domestic and foreign pharmaceutical expansion initiatives, the top priority for China's pharmaceutical distribution sector should be consolidation and integration. In particular, both state-owned and privately owned distributors and foreign investors have made efforts to become a part of China's distribution network, especially in smaller Chinese cities. Examples include:

- State-owned Sinopharm Group Co.'s plans to purchase retail and distribution businesses in smaller Chinese cities
- Investments made by Alliance Boots GmbH, a multinational pharmacy-led health and beauty group headquartered in the United Kingdom, including: (1) the formation of a joint venture in 2007 with Guangzhou Pharmaceutical Corp., the third-largest wholesaler in China; and (2) recent investments in Nanjing Pharmaceutical Co., the fifth-largest wholesaler in China, to become second-largest shareholder
- Privately owned Jointown Pharmaceutical Group's expansion into Sichuan province by way of several joint ventures, acquisitions and collaborations with local distributors

China's Pharma Distribution Sales Exceed $181b (Xinhua News Agency 2013-05-31) – May 31, 2013 According to a report recently released by the Ministry of Commerce, pharmaceutical distribution sales in China surpassed the 1-trillion yuan mark for the first time, hitting 1.12 trillion yuan ($181.2 billion) in 2012. According to the report, although the pace has somewhat slowed, the industry is still rapidly growing. The report demonstrates the expansion of drug sales at the grassroots level and continuous growth of the retail industry, as well as the emergence of effective new service modes as a result of low levels of chain sales.

Traditional Chinese Medicine ("TCM")

News

Chinese and U.S. Researchers Study Tibetan Medicines (Xinhua News Agency 2013-06-19) – June 20, 2013 Researchers from China's Tibetan Medicine External Preparations Engineering Lab (Gansu) and professors from Harvard University's School of Public Health have launched a joint program to study the efficacy of Tibetan medicine, particularly in the treatment of cancer. Studies have shown that a number of traditional Tibetan herbal medicines can alleviate cancer symptoms and even prolong the survival time for some patients. Tibetan medicines include more than 2,000 kinds of herbs that grow in Tibet, Gansu, Qinghai, Sichuan and Yunnan.

TCM Scrutinized for False Advertising (*China Daily* 2013-05-10) – May 10, 2013 Time-honored TCM and related medical services have been hit hard by allegations of false or illegal advisements, according to the country's top TCM authorities at the State Administration of Traditional Chinese Medicine. The department is mainly responsible for keeping TCM medical services in order, as well as overseeing and guiding the assessment of medical advertisements on TCM. Starting in 2008, the department launched a surveillance network targeting TCM-related advertisements in the mass media. By the end of 2012, 534 TCM medical institutions had been warned and fined, 324 suspended from practice, and another 13 had their licenses revoked.

Hospital

News

China Streamlines Health-Related Approval Procedures (Xinhua News Agency 2013-06-19) – June 20, 2013 The National Health and Family Planning Commission ("NHFPC") has delegated approval authority for certain health care issues to local counterpart NHFPC agencies. As a result, the NHFPC has delegated approval authority to provincial-level counterparts for the establishment of mainland health institutions funded by Hong Kong, Macao and Taiwan health service providers. This streamlined movement is part of a cabinet reshuffle plan that was adopted by its legislature in March.

Cross-Species Liver Transplant Succeeds (*China Daily* 2013-05-10) – May 13, 2013 A hospital in Xi'an, Shanxi province, announced the successful transplant of part of a liver from a genetically altered pig to a monkey. The 10-hour operation, the first of its kind successfully performed in Asia, was conducted by a team of doctors at Xijing Hospital of the Fourth Military Medical University. The recipient was a Tibetan macaque monkey, a species found only in China.

Other

China Launches Anti-Trust Investigation into Baby Formula (Xinhua News Agency 2013-07-02) – July 3, 2013 The *Shanghai Securities Journal* recently reported that the National Development and Reform Commission ("NDRC"), China's top economic planner, is investigating several manufacturers of baby formula believed to have engaged in antitrust activities within the Chinese market. Several manufacturers of baby formula, including Biostime, Mead, Johnson, Wyeth, Dumex, Abbott and Nestle, have come under scrutiny for alleged restrictions on prices with distributors and retailers.

Registry to Open for Organ Donors (*China Daily* 2013-06-13) – June 13, 2013 According to the Red Cross Society of China, China will launch its first online volunteer organ donor registry to help ease the shortage of organs for transplant. A volunteer may sign up to become a donor by filling out online forms contained on the website. However, a volunteer may not become a donor if his or her family rejects the option.

China's Health Care Costs Increase: Official Data (Xinhua News Agency 2013-06-19) – June 19, 2013 According to a statistics bulletin released by the NHFPC, health care costs in China increased significantly between 2011 and 2012. In 2012, the estimated total costs of health care services in China reached 2.89 trillion yuan ($473.5 billion) – an 18.8 percent rise compared with the previous year. In addition, the number of medical staff, as well as hospital beds, increased significantly between 2011 and 2012.