

NEWSLETTER

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This newsletter has been compiled by H.J.M. Law & Co., LLC and discussed the current state of the pharmaceutical and biotech industries in the People's Republic of China (the "PRC" or "China").

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I. Summary

The pharmaceutical and biotech industries have grown rapidly in China in the past ten years, in line with the growth levels of the overall Chinese economy. According to Chinese government reports, China is now the ninth largest pharmaceutical market in the world, having an annual growth rate of 16% in 2008¹. Foreign companies are continuing to promote their products in China, and are also continuing to set up joint venture manufacturing companies there, partly due to advantages such as beneficial government policies relating to foreign investment in pharmaceutical and biotech industries, relatively low labor costs and the ongoing reorganization of China's science and technology industries (especially the reform of medical system) which has been ongoing since 1998².

Given the growing worldwide interest in China's pharmaceutical and biotech industries, this newsletter aims to provide information on the relevant markets and a legal overview of the requirements for foreign investors interested in those markets.

II. Market Overview

According to the latest report issued by the national Ministry of Industry and Information Technology of the PRC on March 4th, 2009, the export growth of Chinese pharmaceutical and biotech-related products have been affected by the global economic downturn³. However, production of pharmaceuticals products in

¹ http://www.cccmhpie.org.cn/mid/news_SH_detail.aspx?ID=2007122493541437

² <http://www.l.cei.gov.cn/daily/doc/SXL0B/200810082147.htm>

³ <http://www.miit.gov.cn/n11293472/n11295176/n11299018/12078820.html>. The ratio of export of pharmaceutical products in November 2008 decreased 27.5% compared with that in October 2008 and the number of purchase orders from foreign buyers also lessened.

2008 was 23% higher than the previous year, and biotech products grew at nearly 30% in 2008, which indicate that this industry is still maintaining growth.

In 2007, the pharmaceutical industry underwent, in total, 43 mergers and acquisitions with a combined value of more than USD 3.4 billion, which subsequently resulted in a rise of stronger and more dominant industry leaders⁴. This is evidenced in the report issued by the China Association of Pharmaceutical Commerce (CAPC). In 2007, the sales of the three (3) biggest pharmaceutical enterprises accounted for 19.21% of the total revenue of China's pharmaceutical industry⁵. China's pharmaceutical industry is undergoing systematic globalization, with more and more foreign investors becoming interested in China's pharmaceutical industry. For example, in March 2008, the Shenzhen Hanyu Pharmaceutical Co., Ltd. received USD 15 million from a foreign venture capital firm. Also in 2008, Smart Nice (a subsidiary of Actavis Group) invested nearly RMB 400 million in the purchase of 40% of the shares of Guangdong Techpool Bio-Pharma Co., Ltd..

Since 2004, pharmaceutical companies in China (whether domestic or foreign-owned) have been trying to maximize profit via capital restriction, emergence and integration. In 2007, over five hundred pharmaceutical companies had sales revenue of over US\$7 billion, with the three biggest pharmaceutical companies having annual sales revenue of more than US\$1.4 billion.

Meanwhile, more than three hundred companies, most of which domestic Chinese companies, are involved in the molecular biology industry. This industry is currently focusing on the creation of new products and the provision of services such as health clinics. According to government statistics, China's vaccine market (excluding genetic engineering, antibody drugs and blood products) surpassed USD 4.5 billion in 2007⁶.

⁴ <http://news.pharmnet.com.cn/news/2008/04/17/227495.html>

⁵ <http://60.191.39.27:8008/zjpharm/images/pageImage/a0616.doc>

⁶ <http://www.smehi.gov.cn/data/news/2008/12/02/14575/>

III. Market Trends

Over the next several years, it appears that the pharmaceutical industry will experience the following trends:

A. The rural pharmaceutical market will remain an undeveloped market but with huge potential. With the implementation of the new medical system called the “New Rural Cooperative Medical System”, more than 910 million farmers have been covered since 2002 under this medical system for rural areas in China, accounting for 91.5% of the total farmers⁷ being covered by the new medical system. According to the statistical data provided by the Academy of Macroeconomics Research of the National Development and Reform Commission, the potential size of rural pharmaceutical market in China is more than US\$ 6.4 billion.

However, according to the “Information Times”, 80% of counterfeit and out-of-code products are consumed in rural areas. This may cause issues for the sale capacity and reputation of large drug companies.

B. China will become the largest pharmaceutical research and development (hereinafter “R&D”) base in the world. In recent years, more and more western pharmaceutical enterprises, such as GSK, Roche, and Novo Nordisk, have come to China and set up R&D centers. Nearly forty world leading pharmaceutical companies have established joint venture manufacturing enterprises in China. Some have even set up wholly owned foreign enterprise. Currently, amongst the largest five hundred overseas enterprises having production facilities in R&D centre in the PRC according to law and regulations of the PRC, fourteen of them are pharmaceutical companies.

The main reasons for overseas companies coming to China are cost reductions by using extensive science and technology research infrastructure already in existence,

⁷ http://news.xinhuanet.com/newscenter/2009-01/08/content_10624960.htm

the cheap labor pool, the lower cost of medical and clinical trials, and beneficial government policies.

C. Foreign enterprises will begin a price war in future years in relation to over-the-counter (hereinafter the “OTC”) medicines. Based on expert analysis, foreign enterprises have been closely monitoring the expanding OTC market. In 2007, German pharmaceutical giant Bayer entered into a buyout agreement with Topsun, a Chinese pharmaceutical company, as its strategic investor, aiming to become one of the leading players in China’s OTC market⁸.

IV. Competition

The competition in China is between (and within) both domestic and foreign pharmaceutical companies. There are more than six thousand pharmaceutical factories in China⁹. From 1998 to 2008, pharmaceutical manufacturing output has been increasing at an average rate of 8.4% annually. During this decade, the production of Chinese traditional medicine has increased from 350,000 to 1,270,000 tons and the value of China’s pharmaceutical exportation grew from US\$3.8 billion in 1998 to US\$44.8 billion in 2008. In addition, more and more IT and other companies are investing in the pharmaceutical industry. One example is Fang Zheng Group, an IT company that has, as of 2009, invested a total of US\$363 million into pharmaceuticals and healthcare businesses.

V. Market Access and Entry

The State Drug Administration was established in April 1998 and then changed its name to State Food and Drug Administration (hereinafter the “SFDA”) in April 2003. After the infamous “Zheng Xiaoyu” matter (Mr. Zheng Xiaoyu was the former general

⁸ <http://www.fdinfor.org/CL0033/10753.html>

⁹ <http://money.163.com/08/1015/18/4OALF9KT00252G50.html>

director of the State Drug Administration/SFDA, who was sentenced to death for corruption and subsequently executed on July 10th, 2007), the Chinese State Government decided to merge the SFDA into the Ministry of Health as of March 2008 but the SFDA remains in charge of the administration of food and pharmaceutical products.

All pharmaceutical products to be sold in the Chinese retail market must be registered with the SFDA in Beijing. Depending on the product category, the actual process varies. Most foreign companies still argue that there is a lack of transparency and that they are confused about the complex SFDA registration process. The Chinese government, however, has been trying to improve the market-entry system.

VI. Problems

Intellectual property (hereinafter the “IP”) and an underdeveloped capital market remain the largest barriers to pharmaceutical and biotech growth in China. Venture capital investors require companies in their portfolios to be protected and provide a waiting capital market if they wish to exit. While IP protection is improving in China, and exits are possible on the NASDAQ market through an offshore or US-based incorporation, most venture capitalists remain cautious. Moreover, political opposition from internal R&D departments often discourages foreign companies from seizing pharmaceutical and biotech-related opportunities in China.

A lack of experienced local managers and investors is also a hindrance to foreign participation in China's pharmaceutical and biotech industry. Though many Chinese returnees gain experience abroad before founding a company in China, few have prior executive experience. Because most Chinese biotech companies lack sufficient capital and most domestic venture capitalists lack an understanding of the biotech investment paradigm in developed countries, biotech companies are often forced to adopt complex business models that generate cash flow from a noncore activity such

as distribution. Often, the noncore activity distracts the company from elaborating projects.

VII. Legal Overview

The 'Catalogue for the Guidance of Foreign Investment Industries'¹⁰

In the PRC, different medical industries are treated differently with regards to foreign investment. Basically, investment in the pharmaceutical business should be looked at in view of the 'Catalogue for the Guidance of Foreign Investment Industries' (hereinafter the "**Catalogue**") which is issued by the National Development and Reform Commission and the latest version was issued in December 2007. This Catalogue classifies all industries into three (3) categories, namely encouraged, restricted and prohibited. Any industries that are not listed in the Catalogue are considered permitted industries.

The local governments, economic zones and industrial administrations can make preferential, restricting or prohibiting policies in relation to certain industries (or even sub-industries). The status of each industry varies from region to region, but where an industry is encouraged, it usually enjoys preferential treatment in terms of a speedy registration process, tax advantages and less customs bureaucracy. For encouraged industries (which make up certain areas of the general pharmaceutical industry), a foreign company may possess a majority or all shares of a China-based company in certain areas of the pharmaceutical industry. Those in a restricted industry may be subject to continued (and irritating) scrutiny by the Chinese authorities and also a foreign party may not usually hold a majority of their shares. The permitted industries hold no special privileges for foreign companies or investors (but are nevertheless accessible), and the prohibited industries currently ban all types of foreign entry.

¹⁰ This is the most appropriate translation from the original Chinese text
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The latest Catalogue allowed for foreign investors to invest in Chinese medical institutions. Such investment can only be in the form of a joint-venture. These changes have attracted the attention of foreign investors. However, the wholesale, retail and distribution sectors of the medical industry remain subject to restrictions. For example, majority shareholders of (medical retail) chain stores, which set up more than thirty (30) branches, have several suppliers and sell various types and brands of medicines, must be Chinese companies.¹¹

The following are some examples from the latest Catalogue (2007) of encouraged, restricted and prohibited industries in the medical and pharmaceutical industries. Please note that the biotechnology industry is by-large an encouraged industry.

- Encouraged

The production of new anti cancer medication, new cardio-cerebrovascular medication and new medication relating to the nervous system; production of amino acids; production of new contraceptive drugs and instruments; production of new insect repellents and pesticides.

- Restricted

Production of tetracycline hydrochloride, paracetamol, vitamin B1, B2, C and E and blood products.

- Prohibited

Production of traditional Chinese medicines with ingredients that are considered by the Chinese authorities as rare or endangered (and can include animals or plants), and the production of traditional Chinese medicines that are prepared using a patented method or contain a trade secret recipe.

¹¹ www.docsx.gov.cn/UploadFiles/Up2008313822.doc

VIII. Other Policies

There are some other policies made in recent years by Chinese authorities to regulate or affect the pharmaceutical and biotechnology industries.

In June 2007, the general chief of the 'Department of Price Setting of the National Development and Reform Commission'¹² said to the media that the Chinese government will continue to take measures to reduce the retail price of pharmaceuticals and that the price of pharmaceutical products that are listed under the governmental pricing system will be adjusted twice every year. According to the statistical information provided by the State Statistics Bureau of the PRC, the price of daily-consumption pharmaceutical products have decreased continuously for six years since 2001.¹³

It is suspected that the price of pharmaceutical products will continue to decrease steadily. Future price reductions may originate from pharmaceutical retail shops located in hospitals. Nearly 80% of medicines (both prescription and OTC) are sold through the hospitals instead of the drug retail stores limiting the role of the foreign investor in the retail pharmaceutical industry. It must also be noted that foreign-owned retail drug stores are only allowed to sell OTC medicines and that under current policies, medical insurance market in China is not yet open to foreign investors.

In July 2004, the SFDA announced that pharmaceutical companies producing chemical preparation or any drugs without its issued "Good Manufacturing Practices for the Manufacturing of Drugs"¹⁴ certification must halt production. Since December 2004, all pharmaceutical companies, whether local or foreign, must comply with the

¹² Closest English translation. Found at <http://jgs.ndrc.gov.cn/default.htm>

¹³ <http://www.wxwj.gov.cn/ReadNews.asp?NewsID=2937>

¹⁴ Closest English translation
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Pharmaceutical Management and Quality Standards and obtain GSP (hereinafter the “Good Supply Practice”) certification.

Currently, the imported pharmaceutical product tariff is between 5% and 8% in addition to the usual 17% value-added tax, a total of about 22% to 25%. In 2008, the USA, Switzerland and Singapore proposed that the import duty levied on pharmaceutical products be removed. Such proposal gained the support of the International Federation of Pharmaceutical Manufacturers and Associations but was opposed by most developing countries, including China¹⁵.

In July of 2007, the SFDA issued a new regulation regarding the registration and approval of medical and pharmaceutical products in China. The revision emphasized the following key points and objectives.

The new regulations aimed to pay more attention to safety supervision of medicine and stricter procedural requirements. As a result, the SFDA, under the new regulation, was entitled to carry out onsite checking and sample testing of medicines, as well as simply verifying the authenticity of application documents required for registration. It also prescribed that the acceptance, reviewing, appraisal, and approval process by the SFDA would be open to the public.

In January 7th, 2009, the SFDA issued another regulation related to the detailed implementation rules which prescribed special registration and filing procedures for certain new medicines, such as those relates to AIDS, or those which main components are taken from plants, animals or minerals.

IX. Conclusion

Along with the introduction of new medical reform program in 2009, the Chinese pharmaceutical and biotechnology market may undergo some major adjustments.

¹⁵ <http://www.pharmtec.org.cn/news/hydt/2008-8-2/220.html>

It appears that foreign enterprises will still face barrier to entry, although these will continue to relax. Furthermore, the Chinese pharmaceutical market looks like it will become under the domination of a few large companies. The large import tariffs faced by foreign pharmaceutical companies and high proportion of counterfeit medicines (which are currently not a focus of the Chinese government) further impede foreign company entry. Nevertheless, the easing of restrictions and the widening retail market allow for those foreign companies with an interest in the Chinese market to make possible inroads in 2009. The conditions are getting more suitable for many foreign companies to manufacture their pharmaceutical and (especially) their biotechnology products in China.