

# Chinese pharmaceutical companies: an emerging industry

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As the international pharmaceutical industry strategists grapple with the challenges of new opportunities in emerging markets, not surprisingly, the rapid growth of the Chinese pharmaceutical industry and market has attracted attention as an industry that has good growth in profits. This article will review recent developments and future hopes for the Chinese pharmaceutical industry.

## Overview of the Chinese pharmaceutical industry

China, as one of the most exciting emerging pharmaceutical markets, has been maintaining the production and sales of pharmaceuticals at a double-digit growth (~10%) annually since the mid-1980s. In 1999, the output value of the pharmaceutical industry reached US\$23.4 billion, up 14.2% from that in 1998. Output of chemical drugs experienced 16% growth, whereas the growth of the traditional Chinese medicine (TCM) industry was up by 2%<sup>1</sup>. In 2000, output of chemical drugs was 246,000 tones, up 12.52%, almost half of which was exported, whereas in January–September 2000, exports of TCMs increased by 8.9%, being valued at US\$410,000 million<sup>1</sup>. The biotech industry in China is also becoming highly successful, with sales of biotech products including vaccines valued at only US\$26.5 million in 1996, but exceeding US\$265 million in 2000, hence realizing an average annual growth rate of 20%<sup>2</sup>.

Overall, the Chinese pharmaceutical market and industry is unique in the world. Currently, the market is split



almost equally between chemical and biotech products at 60%, and TCM products (with their roots in Chinese culture) at 40%. Through thousands of years of evolution and recent modernization of the industry with new technologies, TCM products are becoming more acceptable worldwide. The government and the regulators in China are particularly interested in the promotion of the TCM industry, as they believe that these medicines are the most valuable products produced by the country to protect the growth of the Chinese pharmaceutical market against incoming competitors. In fact, the Chinese government has pledged to create several export-oriented TCM company giants in the next 5–10 years.

Another unique feature of the Chinese pharmaceutical market is that it is split

between domestic producers (most of which are state owned), China–foreign joint ventures and imported medicines [these registered through the State Drug Administration (SDA) of China]. It is worth noting that imported medicines made up 40% of the Chinese pharmaceutical market over the past decade.

As China is the world's second largest producer of chemical bulk drugs, and manufactures over 800 chemical drugs to satisfy the demand from the 1.2 billion population, one could be forgiven for thinking that the Chinese pharmaceutical industry would be large. However, the individual companies that produce these drugs are actually small. At present, there are more than 6000 pharmaceutical factories in China, most of them producing single products. The annual sales of the largest of these

companies is only about US\$530 million<sup>3</sup>, just equal to 1% of the annual sales of the US pharma giant Merck<sup>4</sup>. Most Chinese pharmaceutical companies use outdated production facilities, producing raw products with low-tech added value. Furthermore, identical products are manufactured by several factories, making competition naturally ferocious. Currently, little of the profits (about 2% annual sale) is re-invested into R&D of new drugs. In 2000, nationwide total R&D spending on the development of new medical products in China was about US\$500 million, far too small to match international giants such as Pfizer (who spent US\$5 billion), GlaxoWellcome (who spent US\$3.5 billion), and the combined investment of US pharmaceutical producers (who invested US\$26.4 billion) over the same period (<http://www.meinet.com.cn>).

### Government policies

A recent review of the current domestic market and the pharmaceutical industry showed that the Chinese government clearly understood that, although China has emerged to be the world's second largest producer of pharmaceuticals, its industry suffers a serious shortage of investment, little renovative capacity and has few proprietary products. If the anticipated acceptance of China into the World Trade Organization (WTO) goes through, competitors (especially the international giants) will have a devastating effect on the Chinese pharmaceutical industry.

By adopting the Developed World Medicine Policy over the past few years, Chinese policy makers have been able to introduce a central reimbursement list of medicines (the blacklist) to fight the extensive spending on expensive imported medicines. The provinces that followed this policy each made their own blacklist according to their respective different financial and regional situations. As a result, by the end of the third quarter of 2000, Chinese domestic pharmaceutical

companies regained some of their lost profits to realize 50% of the market share, bringing expensive imported medicines down to 22% of the market share<sup>1</sup>.

To increase the capacity of the national pharmaceutical industry, the government is encouraging the research institutes, universities and manufacturers to invest in new product development by intensifying invention protection policy through prolonging protection periods for new applications. This policy has had a profound impact on the effort and investment in R&D in China. For example, the Chinese Military Medical Science Academy filed for patent protection of its new anti-malaria drug, benflumentol, in over 60 countries and regions, and has been approved for marketing in some European and US markets. Clinical trials demonstrated that benflumentol was up to 95% effective in the treatment of pernicious malaria with a post-treatment rate of recurrence of the disease being >5%<sup>1</sup>.

It was reported that a total of 1408 new medicine certificates (NMC) were conferred in 1999 by the SDA<sup>1</sup> (Table 1). The government, through favourable policy, is consolidating state research institutes to strengthen the national research bases. The state has reorganized several key state laboratories to improve aspects such as drug development, clinical studies and pharmaceutical technology development. At the same time, the government has made clear to the industry that it should be the major investor in new product development, and urged it to consolidate itself through mergers and acquisitions and through an increase in investments in R&D.

### Intensifying research capacity

With the rapid growth of the pharmaceutical market in China, most pharmaceutical companies have been prompted to set up their own R&D centres. The new pharmaceutical companies are moving rapidly to establish their own research facilities, whereas the old state-owned

**Table 1. Number of New Medicine Certificates granted in different pharmaceutical company categories in China during 1999**

Pharma company category	Number of NMCs
Chemical	697
TCM	224
Biological	118
Generic	369

Abbreviations: NMCs, New Medicine Certificates; TCM, traditional Chinese medicine.

factories are struggling with serious debts. For example, the 999 Group (Shenzhen, Guangdong), Tasly Group (Tianjin City) and Liu-Ye Pharm (Yantai City, Shandong) have established their own research institutes and have spent millions of yuan on research facilities and recruitment of high-level research scientists.

One further interesting development in Chinese pharmaceutical research is that universities and research institutes of the Science Academy have started to set up joint research institutes with manufacturers that function as economically independent bodies, which are usually located either in the companies or in the universities. Biotech companies are moving even faster in this field. For example, China PKU (Peking University) Weiming Biotech Group has now evolved into a biotech giant in China, with net assets of several hundred million yuan and more than ten wholly owned subsidiaries and joint ventures, including Shenzhen Kexing Bioproducts, Beijing WBL PKU Biotech and Xiamen Bioway Biotech. The group is committed to transforming the newest biotechnology research achievements into products and are mainly engaged in the R&D of biotechnology, as well as mass production and sales of high-tech pharmaceutical products. The Weiming Group sets forth its strategy focusing on pharmaceuticals produced through biotechnology,

including genetically engineered pharmaceuticals, TCM medicines, chemical medicines, biochemical pharmaceuticals, vaccines, diagnostics, agricultural bioengineering and other healthcare products. The PKU Weiming Biotech R&D Centre (Peking University) provides the group with strong technological support.

Another intensified research field is in TCMs. The R&D activity in this field has been put forward by broad establishment of the Medicinal and Biotech-Pharm Research Laboratories, which focus on TCM companies such as Yang-Zhi-Jiang Pharm Group (Chongqing City, Sichuan) and Tasly Pharm Co. Ltd (Tianjin). These companies use the new technologies for the production of their medicines, and their research activities contribute to and benefit the understanding of the mechanism and principles of TCMs to assist these products in entering the international trade market. This has helped products such as the natural component Danshen dropping pill (a cardiogenic pill, used as a treatment for cardiac and cerebral vascular diseases), which can dilate coronary arteries, improve cardiac and cerebral circulation, decrease platelet aggregation and prevent thrombosis. This became the first TCM medicine to pass the Food and Drug Administration (FDA, USA) and was granted IND (investigational new drug) status. Clinical trials of this medicine have now begun in both China and the USA. Since then, a total of 89 TCM products from China have been cleared by the FDA and some of them might soon enter the US pharmaceutical market. In fact, most of the 89 TCM products can already be obtained in the US market as food additives.

### **An emerging biotech pharmaceutical sector**

Biotech globally has experienced rapid growth in recent years and promises enormous potential for future growth. China has pledged not to miss out on

this golden opportunity. In 2000, the biopharmaceutical industry in China was valued at US\$870 million<sup>5</sup>. At present, there are more than 200 companies engaged in the R&D of genetically engineered drugs in China. Among them, over 30 have obtained Trial Production Permits or Formal Production Permits for their products.

In comparison to chemical pharmaceutical companies, the biotech companies in China have developed faster, and there are currently 67 companies listed on the Shanghai and Shenzhen Stock Exchanges. These public biopharmaceutical companies could be divided into three categories based on their business portfolios.

- Specialty biopharmaceutical companies, such as Fuxing Enterprise (Shanghai City), Tiantan Bio (Beijing City), Sansheng Bio (Shenyang City, Liaoning) and Golden Flower (Shandong), all of which have relatively strong R&D capabilities, and use the sales of biopharmaceuticals as their main income. It should be noted that their net profit margins are generally higher than those of the other listed biotech companies in China.
- Companies with biopharmaceuticals as one of their business development directions, for example the 999 Biochemical (Guangdong), Changchun Hi-tech (Jilin), Di'ao Co. (Sichuan), and Huabei Pharma Group (Hebei). These companies are gradually switching their business focus to biopharmaceuticals, and have built up their R&D capability through cooperation with reputable research institutes in China that are able to provide new drug development strategies and strong financial backing.
- Companies that regard biopharmaceuticals as part of their business diversification strategy, including New Huangpu (Zhejiang), Tasly (Tianjin City) and Yueda (Jiangsu).

As a result, 20 genetically engineered medicines have been commercialized in China, including interferon, interleukin, colony-stimulating factor, erythropoietin,

recombinant streptokinase and hepatitis B vaccine. In addition, gene and protein chip technologies have been developed in China. The Biochip Technical Center (Beijing) has started programmes using the gene and protein chips to search for the effective components of known TCMs to find new applications, new therapeutic components, and the mechanism of action of these drugs.

### **Summary**

In recent years, the Chinese pharmaceutical market and industry has expanded greatly in line with the rapid growth of the national GDP. However, China is still a developing country, containing a quarter of the world's population. The cost of medicines consumed per head in China is about US\$20 per year, less than 1/15 of that in the US and Japan, and 1/20 of that in Germany or the UK. Overall, the Chinese pharmaceutical industry has a low capacity, is less innovative and is so small compared with the industry in Western countries that it is unable to compete with the international giants in the USA, Europe and Japan. However, if the current growth trend continues, China will soon become one of world's largest single markets. The pharmaceutical industry in China needs a long period of sustained innovation and investment before it will be able to match the international pharmaceutical giants in their ability to develop novel proprietary medicines.

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