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Trend report:

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China's pharmaceutical market: A new hot spot for pharma companies

- China's pharmaceutical industry continues to grow steadily
- From „imitating“ to „imitating and innovating“
- Increasing M&A-activities in the fragmented competitive landscape

The pharmaceutical industry is one of the fastest growing industries in China. In spite of the global financial crisis and parallel to the development and implementation of a major medical system reform, the Chinese pharmaceutical market continues to signal undiminished growth. The gross production value of China's pharmaceutical industry in 2009 is estimated at RMB 1 trillion with a growth rate of about 30%. According to statistics of the China Information Industry Net (CNII) the production value of the pharmaceutical industry in 2008 totaled 866.7 billion RMB, an increase of 25.7% over the preceding year and higher than the Chinese industry average of 12.9%. Since 2000, the compound annual growth rate of the Chinese pharmaceutical industry's production value has topped 18%. In 2008, almost 7,000 companies produced pharmaceuticals, including more than 4,500 manufacturers of Western drugs. The number of medical device manufacturers exceeded 12,500.

Table 1. Gross production value of China's pharmaceutical industry in 2008

Sub-industry	Production value □ billion RMB □	Growth rate
Active Pharmaceutical Ingredients	185.4	23.2%
Chemical Preparations	233.6	23.9%
Traditional Chinese Medicine	177.9	21.2%
Medical Devices and Medical Auxiliary Materials	75.4	31.4%
Bio-pharmaceuticals	76.9	30.6%
Total	866.7	25.7%

Source: *China's Pharmaceutical Economic News*

Currently, 1,500 types of active pharmaceutical ingredients (API) with a gross production volume of more than two million tons (excluding chemical intermediates and pre-drugs) are produced in China, making China the biggest API producer and exporter in the world. In addition, Chinese companies produce 60 formulations and 4,500 different finished chemical products as well as more than 60 traditional Chinese medicine formulations and 300 biopharmaceutical products, including 20 modern biopharmaceutical drugs. The volume of traditional Chinese medicine products alone totaled 759 thousand tons in 2005.

Approval status of innovative and generic drugs

Over the last ten years, both R&D investment and sales of pharmaceuticals have steadily increased worldwide. However, during the same period the output of new molecular entities (NME) has fallen by 40% in the US and by 20% in Germany. Moreover, a large number of brands face patent expiration, and many pharmaceutical companies are focusing their investment on generic drugs. Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) invested an estimated \$50.3 billion in pharmaceutical R&D in 2008 – up from the previous record of \$47.9 billion in 2007, according to the PhRMA survey. From 2000 to 2007, R&D expenditure of pharmaceutical companies in Europe, Japan and the US increased to more than US\$ 80 billion. However, although large amounts of money are invested in R&D, successful research on new molecular entities is still extremely time-consuming. Only about 8% of the NMEs that enter phase I testing are admitted to the market in the end. Currently, the difficulties of new drug R&D are increasing, and it will be hard to reproduce the approval peak of new drugs in 1995-1999. This furthers the trend towards generic drugs and opens up new opportunities for Chinese manufacturers.

Not sitting back and relaxing despite competitive edge

The key to the competitive edge of China's pharmaceutical companies is the low production costs and huge production capacities. Most manufacturers produce relatively mature generic drugs with simple production technology, avoiding more complex new drugs and technological innovation. The situation is aggravated by the fierce competition: most generic drugs are manufactured by a large number of companies. Antibiotics with high market prices are a striking example: more than 300 companies all produce amoxicillin. Both ceftazidime and ceftriaxone are offered by more than 100 producers. Over 2,000 applications for the approval of generic drugs are filed each year, yet only about 40 newly approved drugs are classified as category 1.1, meaning that they have never been launched before in China or overseas and their API or preparations are produced by synthetic or semi-synthetic methods. Therefore, experts see the necessity for China's pharmaceutical indus-

try to strengthen its R&D investment and move from “imitation only” to “imitation and innovation”.

Table 2. Number of approvals or applications of Chinese chemical drugs

	Number of approved class 1.1 new drugs	Number of generic applica- tions
2007	40	3687
2008	37	2612
2009 (up to Nov.)	42	2445

Note: the definition of class 1.1 new drugs is drugs that have never before been launched in China or overseas, their API or preparations are produced by synthetic or semi-synthetic methods.

Progress in project and engineering technology

In recent years, Chinese pharmaceutical companies have recognized the importance of scientific and technological innovation, and have gradually increased their investment in these fields. As a consequence, processes for the development and production of innovative chemical drugs as well as for new traditional Chinese medicines and new biopharmaceutical drugs have become more industrialized.

Exemplary chemical drugs are Bicyclol, the anti-hepatitis medicine that was approved in China in 2004, or Butylphthalide, the stroke treatment drug that is produced on an industrial scale.

Production technology of the critical nucleus of 7-ACA and 7-ADCA (7-aminocephalosporin acid and 7-aminodesacetoxycephalosporin acid) has also made progress, representing a technological breakthrough for the development of cephalosporins in China. Regarding vitamin E, China has become the world’s main producer due to innovations in synthesis technology and production equipment for the two key intermediates iso-phytol and trimethyl hydroquinone.

The biopharmaceutical sector has also made remarkable progress: the first gene therapy drug worldwide, a recombinant human p53 adenovirus injection targeting a specific form of cancer, was licensed by the Chinese authorities in 2003. Other products that have been launched include recombinant staphylokinase, recombinant humanized anti-human epidermal growth factor receptor monoclonal antibody and a sub-fragment of hepatitis C antibody test kit.

Over the past 2 years, a series of important pharmaceutical projects have been initiated with government support:

- In 2009, HuaBei Pharmaceutical Group invested RMB 2 million in the development of a new industrial park where HuaBei plans to establish a complete production line for the antibiotic cephalosporin.
- In 2008, ChenXin Pharmaceutical demonstrated the production of the anti-hepatitis B virus drug Adefovir on an industrial scale. The company received RMB 10 million in funds from the National High-Tech Industry Development Plan and State Funds Grant Program for this project which included the establishment of an asynthetic production line, a tablet production line and an R&D platform. The project targets a production capacity of 6 tons of the API Adefovir per year.
- In May 2007, with the support of the Biotechnology Center at the Ministry of Science, the pharmaceutical groups ShiJiaZhuang, HuaBei, HaYao and LuKang set up an antibiotics technology innovation strategy alliance. Their co-sponsored project "Innovation in key technologies of antibiotic mass production" has entered the "National Science and Technology Support Program" of the Chinese Science Ministry.

Mergers and re-organizations of Chinese pharmaceutical companies

As the financial crisis impacts the global pharmaceutical market and R&D of new drugs requires increasing efforts, global pharmaceutical companies face the challenge of maintaining stable growth. This in turn is the cause of increasing M&A activity in the worldwide market.

Compared with the global pharmaceutical landscape, the Chinese pharmaceutical industry has a large number of manufacturers, but most of them are small enterprises. The combined sales of the top three Chinese manufacturers account for only 5.2% of the whole Chinese pharmaceutical market. By contrast, the top three pharmaceutical companies worldwide occupy 16.8% of the global market. M&A thus seems to be an inevitable route for the sustainable development of Chinese companies. The reasoning behind M&A transactions is no longer simply to establish a larger-scale company, but rather to combine core competencies along the value chain, create synergies and become the leader in a certain field.

There were 43 acquisitions in the Chinese pharmaceutical industry in 2007, resulting in a total transaction volume of RMB 3.4 billion. Experts believe that there will be even more

frequent M&A transactions in the future. Analysis based on acquisition data from 2004 to 2006 shows that 86% of the funds for acquisitions stem from domestic pharmaceutical companies, of which private enterprises have become the main M&A party. Before entering an M&A project, private enterprises often carry out a thorough due diligence, identify a clear M&A target, and are also quite cautious on the bid. Typical examples are TaiTai's acquisition of the LiZhu Group and Fosun Group's acquisition of several pharmaceutical companies.

Multi-national enterprises account for only 14% of the funds involved in all M&A cases in China, but this proportion is showing growing momentum. The aims of these M&As include the integration of operations in China, access to the Chinese market, exploitation of low-cost manpower and lower environmental investment. An additional motivation for acquisitions in China was the Chinese policy that, up to the year 2000, required foreign companies who wanted to enter the Chinese market to set up joint ventures with a domestic partner. Still, from 2000-2008, besides Bayer's acquisition of the cold drug brands of the Dongsheng Group, there were hardly any large-scale mergers with multi-national companies.

This situation has changed recently, however. Global medical device manufacturer Medtronic spent RMB 1.7 billion on the acquisition of a 15% share in SanDong WeiGao, and established a joint venture. PerkinElmer invested RMB 435 million in the acquisition of Shanghai's XinBo biotechnology company. In 2006, Lilly announced that it would establish a venture capital fund targeting activities in Asia and would invest \$ 10 million in BioVeda Capital, a venture fund directed at the life sciences in China. In November, 2009, Novartis acquired Tianyuan Bio-Pharma in order to enter the Chinese vaccine market. GSK worked together with Yunan Walvax and Haiwang Bio-pharm to establish joint ventures. With the gradual maturing of the Chinese pharmaceutical market and based on its great potential, multi-national and Chinese domestic companies are expected to intensify their M&A activities even more.

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