

China Today: Biopharmaceutical Industry Trends in China—A Five-year Prospective

Now that China has opened its window to the world, its biopharmaceutical industry will see more opportunities

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China's biopharmaceutical industry is entering what some have termed a "Golden Age." The outlook, although generally positive, presents a number of hurdles that may dampen short-term optimism for investors and businesses. But the prognosis, given the current demographic, political, economic, and healthcare situation in China, is positive.

A unique aspect of China's economic planning is its Five-Year Plan, the national economic development guidance that outlines the country's overall development in five-year periods. The Chinese central government established the plan in 1953 as an approach for allocating the national resources necessary for construction, development, and economic expansion. The 11th Five-Year Plan is for 2006–2010.



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This latest plan includes continued investments by the central government in the biopharmaceutical sector to help it become one of the leading industries in China by 2020. The specific objectives for healthcare appear in the "Guidelines for the Healthcare Industry" that were issued last September, based on the national 11th Five-Year Plan.* The principal objectives of the Chinese healthcare industry include:

- Development and commercialization of 10–15 innovative drugs and vaccines with Chinese-owned intellectual property (IP) rights for the treatment of major, acute infective diseases, or chronic severe diseases.
- Marketing five chemical synthetic finished drugs to US or EU countries.
- The country will foster five large-scale pharmaceutical groups with sales revenue of more than 5 billion RMB (\$640 million), promote 10 pharmaceutical distributors with over 3 billion RMB sales revenue (\$384 million), and help five domestic pharmaceutical enterprises evolve into international enterprises.

GROWING PHARMA MARKET

To evaluate the near-term development of China's biopharmaceutical industry, however, it is useful to do more than examine the government's planning goals, BioPlan Associates has developed more specific projections about China's biopharmaceutical industry, based on data and information from the recent study, *Advances in Biopharmaceutical Technology in China*, copublished by BioPlan Associates and the Society for Industrial Microbiology. The study indicates that China's biopharmaceutical sales totaled RMB 30.31 billion (\$3.9 billion) in 2005 and its 2006 sales are estimated to exceed RMB 36 billion (\$4.6 billion). Despite the impact of additional drug price cuts mandated by the government, we predict the Chinese biopharmaceutical industry will continue to see moderate growth through the end of the decade. Over the next five years, we project a rate of 22%, to 80 billion RMB (~\$10.3 billion) through 2010. The primary drivers in the industry will be vaccine and protein therapeutics.

"China's biopharmaceutical industry is now embracing strong development opportunities," said Lifeng Wang, CEO of China National Biotech Group (CNBG) at the First International China Biopharmaceutical Symposium (ICBPS) that was held in Beijing in December 2006. "Chinese biopharma enterprises are looking forward to more collaboration with the world's leading biopharma institutions and companies. We expect to achieve a win-win situation with our global partners. The Chinese biopharmaceutical industry is ready to make significant contributions to global disease prevention and healthcare," she added.

CNGB is the largest vaccine manufacturer in China and controls six biological product research institutes and two manufacturing companies. China's vaccine sector is a bright spot in the biopharmaceutical industry. Because of its population, the country is currently the world's fourth largest vaccine market, following the US, Germany, and Japan. As China's population approaches 1.36 billion by 2010 and 1.45 billion by 2020, the country will most likely become the world's largest vaccine market in the future. This change is driven by market demand, a thriving economy, and an improving healthcare system.

CURRENT SCENARIO

China's biopharmaceutical industry has witnessed 20% to 30% revenue growth annually since 2001. Today, China is home to more than 400 biopharmaceutical manufacturers, including 114 manufacturers of genetically engineered drugs and 28 vaccine manufacturers. Over 30 domestically produced protein therapeutic drugs and 41 vaccines have been commercialized in China. The country also exports vaccines, recombinant insulin, and other biochemical raw materials.

Certainly, in the global landscape, the Chinese biopharmaceutical industry remains small, accounting for less than 7% of the world's total biopharmaceutical market. Also, 95% of the Chinese domestic biopharmaceutical market is made up of biogenerics (copies of biotherapeutics developed outside China). The overall innovative capability of the industry today is quite limited. Most manufacturers are very conservative and their investments in product R&D are small, because of lack of capital and venture capital (VC) support. Government funds and grants are not sufficient to subsidize major research projects at biopharmaceutical companies. As a result, Chinese organizations have sought subsidies and investments from banks and other capital markets, both domestic and international. Today, public and university research institutes receiving government funds play a key role in the R&D of biopharmaceuticals.

In addition to producing a variety of biogenerics to supply its domestic market, China has succeeded in developing and commercializing several innovative biotech drugs and vaccines. Some research-oriented Chinese biopharmaceutical companies such as Shanghai Sunway Biotech, Yantai Medgenn, and Beijing Biotech Pharma have developed a handful of novel protein therapeutic drugs. These companies have won grants from the National 863 Program, a Chinese government-sponsored technology support program that has funded the R&D of more than 300 new biotech drugs across the country. Beijing Biotech Pharma has attracted foreign investment from a variety of sources, including Cuba, but it has yet to see substantial market penetration for its key product—hR3 MAb.

FUTURE TRENDS

A number of trends are emerging in China, including regulatory, enterprise, and IP. Some of these are outlined below.

Regulatory Trends

Increasing government support

In many countries, government support is one of the most important forces fueling biotech development. The Chinese government emphasizes the biopharmaceutical industry in the 11th Five-Year Plan period. China's National Medium-and Long-Term Science and Technology Development Plan Outline (2006–2020) indicates that in the next 15 years, China will deploy a series of cutting-edge technologies in the biotechnology sector. These include target discovery; animal and plant species and drug molecular design; gene operation and protein engineering; human tissue engineering based on stem cells; and a new generation of industrial biotechnology. The government also will increase investment in the biopharmaceutical sectors.

IP protection enforcement

China is making strides in protecting IP rights in conformity with World Trade Organization requirements. This trend will continue in the future, and these efforts are leading to increasing confidence in China's IP protection system. For example, this improved IP protection was a key reason Novartis chose to set up its eighth global R&D center in China in November 2006. Several other multinational companies also have established R&D centers in China.

Regulatory reforms

China's State Food and Drug Administration (SFDA) is modifying policies to encourage innovation and restrict imitation. It is also issuing policies to encourage biopharmaceutical outsourcing. Moreover, the country is on the way to establishing an effective VC system to attract foreign venture capital in the biotech sector.

Drug price cuts

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