

# Development of China's Biomedical Industry and Future Prospects

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## 1. INTRODUCTION

On October 18, 2010, the State Council of the People's Republic of China announced its "Decision to accelerate the growth and development of strategic emerging industries". The seven industries that have been targeted for development are: energy-saving and environmental protection, new-generation information technology, biotechnology, high-end equipment manufacturing, new energy, advanced materials and new energy vehicles.

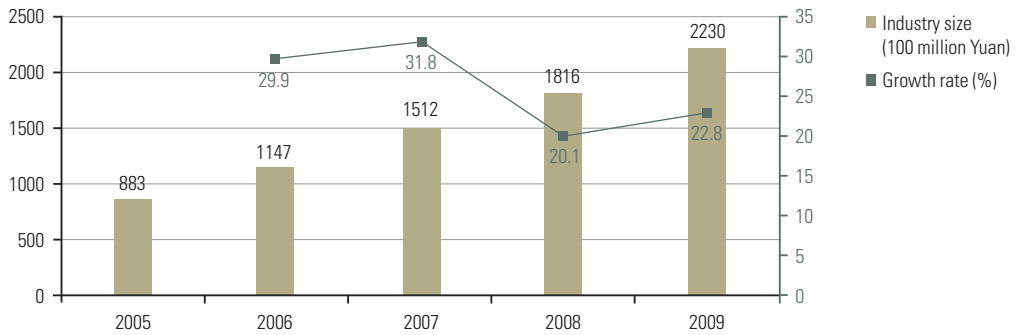
The biotechnology industry occupies an important position among the seven industries. It is one of the fastest growing industries in the world with a 30% annual growth rate in global sales that represents ten times that of economic growth. China's continued advancement in this industry has translated into effectively narrowing the gap between China and developed countries in basic research and technology. Despite the international financial crisis of 2008, it has steadily recorded rapid growth rates. Its growth rate in 2009 increased by 15% and 18% compared to engineering and high-end equipment manufacturing, respectively. The speed of growth and industry size of the bio industry is anticipated to be further elevated with the decision of the State Council.

China's bio industry possesses a history that started in the early 1980s and currently boasts the highest-level of technology in the developing world that even matches global standards in some fields. There are currently twenty-two national-level bio-industrial bases in China. With the adoption of national policies, the bio-industrial base underwent accelerated growth after 2000 and reached an industry size of 2.23 trillion Yuan in 2009.

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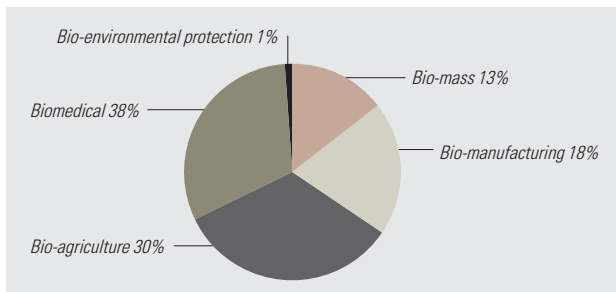
FIGURE 1 Size and Growth Rate of China's Bio-Industry in 2005-2009



Source: CCID 2010. 02

The bio industry can be categorized into biomedical, bio-agriculture, bio-manufacturing, bio-mass and bio-environmental protection. The biomedical industry occupied the largest proportion in the Chinese bio-industry in 2009 and this paper forms an analysis of China's core biomedical industry.

FIGURE 2 Industry Composition of China's Bio-Industry in 2009



Source: CCID 2010. 02

## 2. CURRENT STATUS OF CHINA'S BIOMEDICAL INDUSTRY

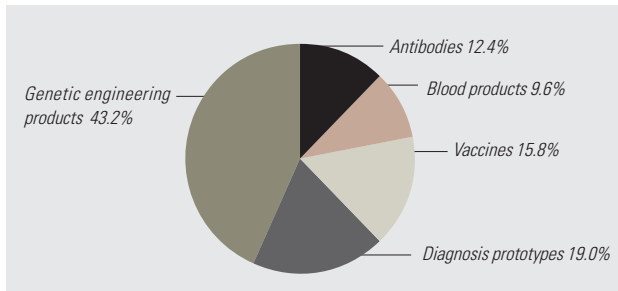
Over the past two years, the Chinese biomedical industry withstood the challenges of the 2008 global financial crisis and resumed accelerated growth in 2010. Bio-technology continues to undergo development that invigorates market demand. Multi-national companies are quickly entering the Chinese market, and the shaping of an industry-friendly policy environment (such as medical insurance reform and strategic emerging industry policies) poses both challenges and opportunities for the biomedical industry.

### 2.1 Industry Architecture

Vaccines, including anti-tumor drugs, autoimmune disease drugs, and anti-diabetic agents, were crit-

ical to the biomedical industry, and recorded the highest growth rates among bio-tech products. The global biomedical industry was composed of genetic engineering products (49.4%), diagnosis prototypes (18.0%), antibodies (14.2%), vaccines (9.4%) and blood products (9.0%) in 2009. The case is similar in the Chinese biomedical industry, with genetic engineering products (43.2%), diagnosis prototypes (19.0%), antibodies (15.8%), vaccines (12.4%) and blood products (9.6%). Recently, the biomedical industry has flourished remarkably and there are currently more than seven hundred enterprises operating in the industry. The industry has grown by 24.6% year-on-year and represents 85 billion Yuan as of 2009. Biomedical and bio-breeding are among the national strategic emerging industries and represents a significant new opportunity for future growth in the Chinese biomedical industry.

FIGURE 3 China's Biomedical Industry Structure in 2009



Source: CCID 2010. 02

## 2.2 Main Features

**2.2.1 Rapid growth driven by market demand:** Since 2003, the market size of the global biomedical industry increased by more than 10%; however, this was surpassed by the annual growth rate in China of 25%. The Chinese biomedical industry managed to maintain its exceptionally strong growth rate due to various elements, including accelerated economic growth, an ageing population, improvement of individual living standards and greater health consciousness. Huanlan Bio and other Chinese biomedical enterprises made advances in sales and net profits in 2010. The industry grew into a market of more than 110 billion Yuan in 2010 and recorded an 18% growth over the previous year.

**2.2.2 Higher growth potential due to favorable policy environment:** The policy environment is always a critical factor in the growth of the biomedical industry. In June 2009, The State Council announced “Several policies to facilitate the development of the bio-industry” followed in October 2010, by its “Decision to accelerate the growth and development of strategic emerging industries”. The biomedical industry was selected as a strategic emerging industry that the Chinese government would concentrate on fostering. China’s biomedical products harbor great market potential; in addition, the abundance of bio-genetic and human resources in the country represent a particular advantage. The R&D investments in the industry by central and local governments over the past two years exceeded 30 billion Yuan. Various policy factors, such as basic vaccinations and the reform and proliferation of medical insurance led to many opportunities for advancement in China’s biomedical industry.

**2.2.3 Driving engine of related industries:** The biomedical industry value chain is composed of basic research, testing, development, manufacturing, and sales. Large traditional pharmaceutical companies customarily cover all phases of the value chain independently. However, progress in the bioindustry in the 1970s completely transformed the industry pattern of biomedical. This inevitably brought change to the value chain. The biomedical industry no longer focused on the last phase of the value chain and began to expand upstream.

**2.2.4 Industrial development limited by lack of innovative investment:** The reason speed of growth in the biomedical industry has been higher than that of chemicals, pharmaceuticals and traditional Chinese Medicine; however, its position in the market is still relatively low. In 2010, the industry's production and R&D costs occupied 11.5% and 11% (respectively) in the overall pharmaceutical field. In particular, technology R&D and commercialization capability are critical to the industry, but the lack of innovative investment and an imperfect investment financing system act as the largest obstacles to industrial development.

### 3. REGIONAL DEVELOPMENT PATTERNS

In 1989, China's first bio-enterprise, Shenzhen Kexing Biotech, was born. It heralded the beginning of the biomedical industry in China. The industry took off as industry complexes began popping up nationwide.

#### **3.1 Core Regions in China's Biomedical Industry: Bohai Economic Rim and Yangtze River Delta**

Industry allocation is distinctive since the biomedical industry was established across China at varying times. Currently, a new industrial pattern is being shaped with the fast growth recorded by central and northeast regions led by the Bohai Economic Rim and Yangtze River Delta, including the Pearl River Delta and Northeast region. Typically, the industry requires significant investment, entails high risks, offers high returns, and long R&D periods. Therefore, it tends to settle in regions with an established industrial complex, a high level of economic development and professional human resources. The growth imbalance between different regions in China's biomedical industry is expected to widen during the 12th Five Year Economic Plan. In particular, R&D and clinical test phases will continue to be attracted to research institutes located in the eastern coastal regions such as Beijing and Shanghai.

The Bohai Economic Rim has the most human resource professionals, clinical tests, and education resources. Notably, Beijing in the northern region is home to many research institutes and rich in skills human resources that make it a core region for technological development, information services, and technology services.

As for the Yangtze River Delta, it is a region with the greatest number of multinational biomedical enterprises. Its comparative advantage in R&D, commercialization, outsourcing and international cooperation, has led to the gradual formation of biomedical industry complexes around Shanghai. Shanghai is a region that boasts the latest cutting-edge biomedical technology and highest industrial foundation standards in China and is why it has managed to host the greatest number of multina-

tional biomedical enterprises and international financial institutions. Shanghai is the hub for R&D, manufacturing and production, marketing and investment in mainland China. It is the heart of the Chinese biomedical industry.

### **3.2 R&D-Oriented Enterprise Concentrated Regions: Beijing and Shanghai**

Many biomedical firms are based in Beijing and Shanghai. There are a hundred such companies located in Zhongguancun Life Science Park and Yizhuang Biomedical Park in Beijing. Two hundred and ten companies have been established in the Zhangjiang High-tech Industrial Development Zone in Shanghai Pudong. The companies here can be largely categorized into three groups: companies committed to R&D but stuck in the incubation stage due to a lack of a commercialized product, highly-profitable companies that can lead the relevant field with patents or patented technologies, and R&D centers of foreign biomedical companies based in China.

Beijing and Shanghai are popular locations for R&D-oriented companies as they can provide the necessary resources and conditions for the advancement of businesses.

**3.2.1 High R&D basic skills and numerous research institutes and universities:** Prominent biomedical R&D institutes are located in both Beijing and Shanghai: a total of nine medical universities and graduate schools, together with biomedical R&D institutes, such as the Chinese Academy of Sciences, Chinese Academy of Medical Sciences, China Academy of Chinese Medical Sciences, Academy of Military Medical Sciences, Shanghai Institute of Pharmaceutical Industry, Beijing University, Tsinghua University, Fudan University and Shanghai Jiatong University. Some R&D institutes have also set up businesses in these cities. For instance: Tian Yun, a major vaccine business (listed on the Shanghai Stock Exchange) was established by reorganizing the Beijing Bio-product Research Center. Kexing (listed on the NASDAQ exchange) shares a deep history with Beijing University. Bio-Sino (listed on Hong Kong Exchange) was originally an affiliated company established in 1988 by the Institute of Biophysics, Chinese Academy of Sciences.

**3.2.2 Human resources advantage:** The biomedical industry is a hi-tech field and has a high demand for professional human capital. The greatest number of China's professional human resources flock to Beijing and Shanghai. This enables medical schools and institutes to produce many professionals as well as facilitates the recruitment of talented applicants.

**3.2.3 Numerous large hospitals and abundant clinical test resources:** A number of major hospitals are situated in the two cities. Beijing has 53 of the ranked hospitals (Level Three Grade Gap) in China, and Shanghai has 37. These hospitals have a high level of skill in all medical fields that attract many patients nationwide. This also means a larger number of subjects available for clinical tests. Furthermore, there are dozens of Collaborative Research Organizations (CROs) in Beijing and Shanghai. Their main role is to provide professional clinical test research services to local and foreign medical enterprises.

**3.2.4 Financial capital support:** Shanghai founded the Biomedical Investment Fund and Professional Investment Company through the integration of available government investment funds. Simultaneously, its advanced financial system facilitates the progress of the biomedical industry. It tries to attract as many private investments as possible and nurture major businesses. In step with advances made in industrial clusters, it established the Engineering Technology Center and GMP Test

Station. It resolves issues that can surface during the commercialization processes (such as technology bottleneck and poor funding) that provides support to businesses stuck in the incubation phase and enables them to succeed in commercialization.

The Beijing Municipal Science and Technology Commission announced “Measures to encourage finance and work management to facilitate the rapid growth in Beijing’s biomedical industry” together with the Marketing Management Department of the People’s Bank of China and the Beijing Banking Supervision Department of the China Banking Regulatory Commission in April 2010. A total of 11 banks and asset-backed lenders participated in this plan. Furthermore, by establishing the Venture Support Fund, it encourages financial institutions to increase the financial support capacity to assist biomedical enterprises that undergo new drug tests, commercialization, technological development and market expansion.

**3.2.5 Broad international exchange, attraction of foreign medical R&D centers and venture investments:** Beijing and Shanghai engage in active exchanges (in terms of politics and economy) with developed regions such as North America and Europe due to their special position in China. This is why they are optimal stepping stones for foreign medical R&D centers wishing to enter the Chinese market. The world’s top 20 medical enterprises installed for R&D centers in Beijing and six in Shanghai. Furthermore, venture investment companies of developed countries are fascinated with the biomedical enterprises in Beijing and Shanghai. Most of the recent overseas venture investments in the Chinese biomedical industry were concentrated in these two regions. Some examples in from Shanghai are Nuokang Biopharma, Nuodanmai, Kaisere, Huada Tianyun, Kemei Dongya and Kunaoji.

### **3.3 Product Manufacturing: Shandong Province, Jiangsu Province**

Shandong and Jiangsu Provinces are regions with the greatest production of biomedical products. The total production of these two regions alone accounted for a third of the entire national production; however, neither province possesses a comparative advantage in terms of R&D or human resources. Their high market share can be explained by the many companies that can mass-produce.

Shandong and Jiangsu Provinces were traditionally known for manufacturing. In particular, they have extremely strong industrial foundations in medical and chemical engineering. Shandong Province has seven bio-industrial complexes (Dezhou, Qingdao, Jinan, Zhibo, Yucheng and Yishui) and large medical enterprises (such as Lunan, Jilu, Xinhua, Dongeejiao and Furuida); in addition, it has established a complete biomedical product manufacturing chain based on five medical sectors (genetic engineering products, fermentation technology products, bio-chemical products, new diagnosis prototypes, and marine products).

In comparison, major players in the biomedical industry are based in Jiangsu Province and 17 enterprises are ranked among the Top 100 Pharmaceuticals. Yangzijiang Pharmaceutical is one of China’s largest pharmaceutical companies. At the same time, the region managed to attract many multinational factories. Equipped with state-of-the-art manufacturing technology, Jiangsu is planning to construct Nanjing, Suzhou and Lianyungang biomedical bases around China’s Pharmaceutical Office in Taizhou.

### **3.4 New Regions of Biomedical Development**

The Pearl River Delta is a region where logistics flourished and private capital developed due to its

geographical vicinity to Hong Kong and Macau. In particular, Shenzhen is expected to undergo expedited progress in R&D standards for life science research and bio information safety that has the potential to grow into the future hub of gene technology and bio-information.

The Cheng-Yu Economy Zone thrives with innovative activities in the bio medical sector and represents an important biomedical performance transfer base in the western region. Changchun City and the surrounding Chang-Ji-Tu region is one of Asia's largest vaccine manufacturing bases. As for Chang-Zhu-Tan, it has a strong industrial foundation and is home to the biomedical industrial complexes of the Changsha High-tech Industrial Development Zone and Liuyang Biomedical Park. In addition, some 300 R&D institutes and well-known companies are located in Wuhan City that creates an environment of innovation and a full industrial development process. Regions such as Taiyuan(Shanxi Province), Xiamen(Fujian Province) and Lanzhou(Gansu Province) either are rich in resources (such as manufacturing materials) or have hosted major companies that represent a source of important progress in the biomedical industry.

## **4. FUTURE PROSPECTS**

### **4.1 Driver Effect in the Medical Market**

The biomedical industry has the highest growth potential and advances at the fastest speed in the entire medical market. China's biomedical enterprises mainly manufactured copy products for a long time and the extent of duplication in construction is large with most of the businesses small. In particular, they have poor manufacturing levels, a lack of R&D investment and a meager share of the market. However, China's announcement of policies (such as the Biomedical Industry Promotion Plan and 12.5 Plan) will channel more policy support towards the biomedical industry that will eventually result in significant changes to the medical market architecture.

### **4.2 Driver Effect in the Outsourcing Industry**

With the rise in the complexity of biomedical technology and the adoption of a stricter new product certification system and a product price ceiling system, lowering unit costs has become an important factor to enhance corporate competitiveness for biomedical enterprises. A growing number of multinational companies prefer to consign the development and manufacture of certain new drugs to another specialized company. China's biomedical outsourcing service industry will advance further as the new product development and manufacturing functions of multinational companies gradually transfer to mainland China.

Multinationals have recently begun to transfer R&D and manufacturing arms to India and China in order to reduce unit costs. Technological services that cover all phases of new product development (from development to pre-clinical tests, clinical tests, data management and new product registration) can be outsourced. The achievement in the central section of the value chain (the product test phase industry) is notable. The current size of the global biomedical outsourcing market reached 36 billion USD with an annual growth of 16%. China is ranked No. 1 for R&D and manufacturing outsourcing due to its abundant human resources and low unit costs. In Shanghai, a leading pharmaceutical company Yaoming Kangde and genetics enterprise Ruizing are already outsourcing overseas and Yaoming Kangde has entered into outsourcing contracts with eight of the world's Top Ten biomedical firms.

### **4.3 Promising Chinese Biomedical Industry Sectors in 2011**

Medical insurance reform and the State Council's "Decision to accelerate the growth and development of strategic emerging industries" have reinvigorated the biomedical industry that has already enjoyed long-term attention. In regional governments, it is once again a hot issue of industrial development. Vaccines, genetic engineering, and test reagents are among the most talked about sectors of social capital. The high risk-high return biomedical industry requires high investment capital; however, the desirable policy environment and government investment support can effectively lower corporate investment risks. This favorable environment will help propel industrial growth once social capital is channeled into the industry.

Specifically, the Grade 2 Vaccine (vaccines not covered by medical insurance) sector is anticipated to undergo significant growth in 2011. Its market share in the vaccine market is expected to rise by 25%, and market demand for unexpected epidemics, including vaccines to treat Hepatitis B, AIDS, GH (growth hormones) and H1N1, will continue to grow. Social capital will also be injected in large amounts to sectors with great growth potential, such as genetic engineering sectors that include recombinant proteins to treat cancer and monoclonal antibodies, insulin and test reagents.

### **4.4 Outlook on Industrial Development Trend**

The Chinese biomedical industry is expected to maintain its relatively high growth rate throughout 2011 due to the industry-friendly policy environment. The Chinese government announced its 12th Five Year Plan for the biomedical industry. The respective sectors for concentrated cultivation include gene therapy, protein therapy, monoclonal antibody, treatment vaccines; in addition, small molecular chemical drugs, biomedical innovation, and industry upgrades are among the Top Nine major projects. Specific field policies and regional government support policies (Major Contagious Diseases Project, Drug Registration and Management, Medical Device Management, and TCM Injections 689 New Technology Standard) will be implemented in the near future along with sector plans for the industry (medical insurance reform, addition of basic drugs, new GMP, Biomedical 863 Plan and Vital New Drug Development Project).

Growth in the Chinese biomedical industry will also continue to accelerate because the industry has already entered the expressway for industrial development. In the next decade, gene therapy methods and products will enter the final development phase and move to the application phase. Major fields, such as cancer treatment, cardiovascular disease, high blood pressure, diabetes and neurological disorder, will see the development of 200 biomedical products and the beginning of clinical tests for some 400 biomedical products. The R&D and commercialization capability of China's biomedical industry will improve considerably and continue to expand the market potential.

### **4.5 Product Innovation**

The role of innovative medical products is very small in China. Among registered products every year, 90% are related to generic drugs. Furthermore, the commercialization of biomedical R&D acts as an impediment to industrial advancement. During the 12.5 Plan, the industry will continue to pursue its past strategy of "New product development through major projects". Major national science and technology projects and the 863 Plan Project that include major new drug development, cure of AIDS and viral hepatitis, stem cells and tissue engineering, antibodies and vaccine engineering, functional gene composition proteome, and biomedical sector, will soon be implemented.

The "Major New Drug Development Project Plan 12.5" is being prepared for implementation.



According to the plan, approximately 10.5 billion Yuan will be invested in the development of major new drugs and 10-60 million Yuan will be injected in support of each technological development platform. Year 2011 will see more expansion in policy and financial support in the biomedical industry by the Chinese government with a focus on new product development, industrial restructuring and industrial upgrades.

#### 4.6 Conclusion

China's biomedical industry is a market with remarkable potential. The next five years will be an important growth period for the industry. The current global biomedical industry has yet to witness the monopolization by a handful of multinational companies. China is expected to catch up surprisingly quickly because there is a limited gap between China's biomedical technology, talented human resources and R&D foundations and those found in advanced countries.

China is the world's greatest market. The extensive market demand potential directly acts as a stimulating factor that can propel the rapid growth of the biomedical industry. The Chinese biomedical market is expected to grow into a considerable industry due to the continuous improvements in medical coverage for the Chinese population of 1.3 billion. Factors, such as medical insurance reform, population increase and ageing will raise the demand for all kinds of pharmaceuticals. Changes to products covered by medical insurance will also increase the proportion of biomedical products. The industry is expected undergo accelerated growth during the implementation of the 12.5 Plan and the Chinese biomedical industry market is forecast to reach 40 trillion Yuan by 2020

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