

The development of Bio-pharmaceutical industry in China: Problems and solutions

Gujun Yan

College of Economics, Zhejiang University, Hangzhou, P.R. China

Abstract: Known as the "sunrise industry" of the 21st century, bio-pharmaceutical industry has been a fast-growing global industry, and many countries have been developing this industry as the focus of their national economies. In China, there exists a huge market demand for the development of bio-pharmaceutical industry, but at the present stage the industry is faced with some problems, such as low level of R&D for innovative drugs, and inappropriate capital investment in the industrialization. In order to accelerate the development of China's bio-pharmaceutical industry, it is necessary to take strategic initiatives of improving the technology transfer system, developing the bio-pharmaceutical outsourcing, and building a diversified industrial financing system.

Keywords: Bio-pharmaceutical industry, independent innovation, biomedical outsourcing, venture capital.

INTRODUCTION

Bio-pharmaceutical industry refers to economic activities of mass production of marketable drugs through the application in pharmaceutical industry of the research results of modern biotechnologies, such as genetic engineering, cell engineering, enzyme engineering, fermentation engineering and protein engineering. Currently, modern bio-pharmaceutical industry's main products include genetically engineered drugs, antibodies, vaccines, blood products and diagnostic reagents. With recent rapid advances in biotechnologies, bio-pharmaceutical industry has achieved rapid development. In many countries, biomedical industry has been identified as a key industry in the 21st century (Li, 2012; Sheng *et al.*, 2012; Zhu *et al.*, 2012).

In 2009, China officially launched a new round of medical and health system reform (Ling, 2012). According to the reform plan, China's basic medical insurance will cover more than 90% of urban and rural residents; that is to say, more than 12 million residents will have access to basic health care, which will release enormous potential for health care spending, and bring a broad development space for bio-pharmaceutical industry. However, there are still some shortcomings related with this industry at present, such as irrational industrial structure, weak independent innovation capability, and so on. So, on the basis of existing foundations and advantages, how should China do to accelerate the development of bio-pharmaceutical industry and further enhance the strength and competitiveness of that industry as a whole? Based on the analysis of the status quo and existing problems of China's bio-pharmaceutical industry, this paper puts forward some countermeasures for speeding up the development of biomedical industry.

Development status of bio-pharmaceutical industry in china

In comparison, the bio-pharmaceutical industry is characterized with high-tech, high investment, high-risk, high-yield and long-cycle (Niu *et al.*, 2012; Xu *et al.*, 2012; Zhang *et al.*, 2012). High-tech is mainly reflected in high required technical levels, the complexity and variety of the technologies; high investment is mainly reflected in the substantial inputs at the R&D stage; high risk is reflected in the technical aspects, market and policy factors; high-yield is embodied in the returns of successful projects, often up to 10 times more; Long-cycle refers to the long period between R&D and the final products, which may often need to go through basic research, applied research, pilot, animal testing, clinical trials, large-scale production, product marketing and other aspects. From the perspective of industry chain, bio-pharmaceutical industry can be divided into three links of upstream, midstream and downstream. Upstream mainly refers to the research and development stage, including technical innovation and drug discovery; midstream is the stage of drug development, including pre-clinical tests and clinical studies; downstream mainly refers to drug production and marketing links (see fig. 1).

Since the 90's of the last century, biomedical industry in China has obtained certain development through ways of the imitation of foreign products and increasing the research of innovative drugs.

Fast industry development

In recent years, China's bio-pharmaceutical industry has maintained rapid growth. During 2006-2010, the annual output value of the industry grows 23.8% on average, and the market size rises from the ninth place in the world to the third place. In 2011, the scale of China's bio-pharmaceutical industry reached 1.5 trillion RMB Yuan, accounting for 3.5% of the total national GDP. By 2015,

*Corresponding author: e-mail: zjujt@163.com

China's biomedicine industry output is expected to exceed 3 trillion RMB Yuan. At present, China's pharmaceutical enterprises involved in modern biological technology is about 500, with approximately 50,000 employees, and nearly 100 new biomedical companies are created every year.

Growing scale of the industrial parks

In recent years, driven by national policies and strong development potential, “medicine-valley-fever” continues to heat up, and various kinds of such projects have been intensively launched. At present, the number of all kinds of “medicine valley” is no less than one hundred, of which approved by the relevant state departments or local governments is more than 50. Biomedical industry parks have become the main carrier of China's biomedical industry cluster-style development (table 1). Some industrial parks have signed cooperation agreements with internationally renowned enterprises, science and technology parks, investment institutions and universities, and these parks' overall innovation capability has been enhanced. Overall, the industrial parks are driving the rapid development of biotech-industry.

Increasing investment from multinational pharmaceutical companies

With the rapid and sustained growth of Chinese pharmaceutical market, the multinational pharmaceutical giants have shifted their focus of pharmaceutical marketing to China. In addition to introducing new drugs to China, foreign-funded enterprises also began to layout the introduction and production of generic drugs, accelerate the establishment of R&D centers in China, and speed up the acquisition of Chinese pharmaceutical companies. Currently, the world's top ten pharmaceutical companies have set up plants or R&D centers in China, and their market entry ways have changed from the traditional prescription drug sales to strategic layout of the

whole industry chain (Liu, 2012). The integration of multinational pharmaceutical companies into Chinese medicine industry, on the one hand, may play an active role in promoting the development of Chinese medicine economy, and on the other hand makes Chinese bio-pharmaceutical enterprises face more open and fierce global competitions.

Considerable degrees of reserves in talents and technology

Currently, personnel engaged in biotechnology research and development in China is near 20,000. Meanwhile, an increasing number of overseas students studying abroad returned homeland, and brought a number of advanced technologies. In addition, China has special biological resources, which provides a unique resource for the disease-related genetic research. Furthermore, a series of policies to promote the development of bio-industry has also been unveiled by the Chinese government in recent years.

Problems existing in the development of biomedical industry in china

Low level in innovative drug R&D and industrialization

The development of innovative drugs, can not only elevate the brand effect of enterprise, but also bring huge gains. However, most pharmaceutical companies still give priority to producing generic drugs, thus lack of independent intellectual property rights and brand effects. Also, many enterprises are at the lower position in the value chain—drug substance manufacturing. Currently, innovative drug R&D and industrialization level is still very backward in China; really matured biomedical products with high added value that can be rapidly industrialized is very limited. For example, enterprises that have production capacity of genetically engineered drugs only account for less than 1/3 of the entire biopharmaceutical companies in China. To a certain

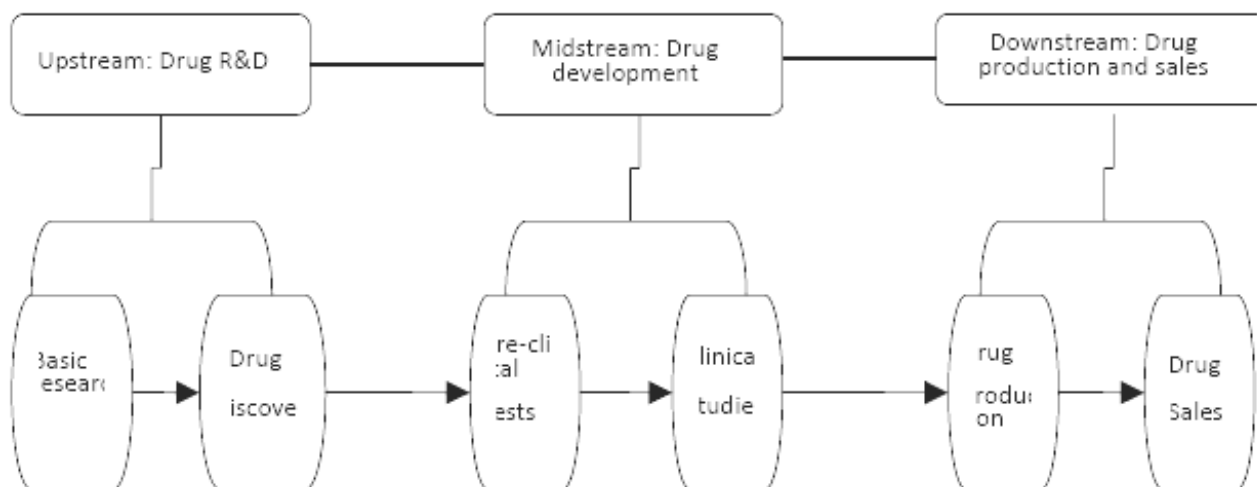


Fig. 1: Bio-pharmaceutical industry chain

extent, China's bio-business is just as producers, often unable to stand in the forefront of biotechnology.

Unreasonable capital investment in industrialization of biological medicine

Abroad statistics in recent years show that an innovative genetic engineering drug or stem cell drug, takes an average of more than 13 years in R&D and more than \$ 800 million in funding. Although China has abundant human resources and the advantage of lower labor costs, strong financial support is still necessary for the development of biomedical industry. In recent years, inputs by the government for biomedical innovation are growing, but most of the funds are used to support basic scientific research. Basic scientific research is very important, but is often out of touch with the industry. In the future, China should increase funding to technologies that are more close to the industrialization. At the same time, some pharmaceutical companies focus more on construction of factory buildings, instrument and equipment, and does not attach importance to investment in product development and technical innovation; they also invest less in the development of bio-pharmaceutical market, thus not conducive to product sales and the realization of profits after product listing.

Bio-pharmaceutical enterprises being small and scattered

According to incomplete statistics, China has more than

4,000 pharmaceutical companies, but no one can enter the world's top 500 enterprises. This leads to low industrial concentration of bio-enterprises, structural convergence of the development, market disorder, and weak international competitiveness. For a long time, many companies in China mainly produce chemical medicine, and are not fully adapted to more strict production process for biotech drugs, so they are difficult to reach the CGMP standards recognized by some countries.

Limited financing channels

In other countries, the funds necessary for the bio-industry development mostly depend on government financial support for basic research and capital markets. However, capital source channels of biological medicine industry in China are limited. Bio-pharmaceutical firms are mainly financed through self-financing, government grants and loans from financial institutions. Among them, self-financing is dominated; funds from capital market and private capital is not much. In fact, bio-pharmaceutical industry is characterized by high-risk and high profitability and thus requires investments from risk-taking venture capitalists (Baeyens *et al.*, 2006; Nickisch *et al.*, 2009). In China, venture capital exit mechanism has yet to be improved, and such capital is difficult to quit, thus increases the risk of investors. Consequently, even though venture capital in China is active, it has been in a state of wait-and-see.

Table 1: the size and value of some biomedical industry parks in China

Park name	Size of the park (Number of enterprises settled)	Gross output value of the park
Wuzhong medicine industry base	About 90 (As of the end of 2010)	8.5 billion Yuan (year 2010)
Limin new medicine industry base	60(As of the end of 2012)	13.5 billion Yuan (year 2007)
Liuyang biomedical industry base	More than 110(As of the end of 2011)	25.2 billion Yuan (year 2011)
Changzhou Xinbei district "Sanyao" Science and technology industrial base	93(As of the end of 2011)	N.A.
Taizhou medicine industry base	More than 550(As of the end of 2011)	43.13 billion Yuan (year 2011)
Dalian Port double-D biomedical industry base	More than 60(As of the end of 2010)	N.A.
Xi'an High-tech Zone biomedical industry base	More than 280(As of the end of 2010)	N.A.
Hohhot biological fermentation distinctive industry base	N.A.	9.96 billion Yuan (year 2009)
Qidong biomedical industry base	N.A.	4 billion Yuan (year 2009)
Dunhua traditional Chinese medicine industry base	N.A.	2.38 billion Yuan (year 2010)
Zhejiang Xianju steroid drugs distinctive industry base	N.A.	2.54 billion Yuan (year 2010)
Guangzhou national bio-industry base	More than 220(As of the end of 2010)	42 billion Yuan (year 2011)
Qingdao national bio-industry base	More than 300(As of the end of 2010)	15 billion Yuan (year 2010)
Harbin biological industry Base	150 (As of the end of 2010)	21 billion Yuan (year 2010)
Tonghua biological industry base	94 (As of the end of 2010)	30.48 billion Yuan (year 2010)
Chengdu biological industry base	230(As of the end of 2010)	N.A.

Source: Wang *et al.* (2012).

Inadequate intellectual property protections on biomedical industry

Intellectual property rights are essential to innovation and development of the bio-pharmaceutical industry. Only by establishing a sound intellectual property system, can the development of bio-pharmaceutical industry form the virtuous circle of “innovation-protection-innovation again”. Due to the lack of protection consciousness and talents, protection on intellectual property related with biomedical field is inadequate. Both the application of and the protection on patents of biomedical research achievements have a big gap with foreign countries, which result in some high value research results failed to properly obtain patent protection. Moreover, when cooperating with industrial companies, China's biomedical research institutions often cannot accurately assess the value of their research achievements.

Strategies to promote the development of bio-pharmaceutical industry in china

Under the action of rapid economic development, constantly rising of people's income level and the ageing of the population, China's pharmaceutical market remains an annual growth of more than 20% over the last ten years. It is predicted that by 2018, China will surpass Japan to become the world's second largest pharmaceutical market. The rapid growth of China's pharmaceutical market will bring space to the development of biomedical industry.

To improve the ability of independent innovation

Innovation is the most fundamental impetus to the development. The research and development of new drugs with independent intellectual property rights, is the only way for China to be transformed from pharmaceutical production giants to pharmaceutical power. It is time to accelerate the construction of an innovation system with enterprises as the main body of innovation, strive to develop cutting-edge, common and core technologies, and develop a number of the world's advanced level products independently. The current status of focusing only on laboratory construction, laboratory research and paper publishing need to be broken; the construction of test base, clinical base and industrialization base should be emphasized; research groups covering biomedical application basic research, applied research and development research, should be formed.

To improve the technology transfer system

According to statistics, the conversion rate of technological achievements from research institutes is only about 20% in China, which is far lower than the developed countries' level of 60-80%. The main causes of the above situation are that the research directions of the scientific research institutes are not directly market-oriented, and the technological achievements of these institutes are often out of touch with the technical

difficulty of the enterprises. In addition, the delayed development of sci-tech intermediaries and professional talents engaged in technology transfer is also one of the reasons. Therefore, it is necessary for China to actively organize various forms of high-level biomedical communication activities between research institutions and enterprises, and further improve the technology transfer system to facilitate bio-pharmaceutical enterprises to attract domestic and foreign advanced technology. Also, China should actively establish and improve the science and technology intermediary service system by fostering the development of technology intermediaries and cultivating a large number of interdisciplinary talents engaged in technology transfer.

To actively develop bio-pharmaceutical outsourcing

Since bio-pharmaceutical industry has characteristics of high-tech and high investment, individual enterprise is difficult to operate the whole industry chain, and outsourcing flourishes in that industry (Chen *et al.*, 2010; Lowman *et al.*, 2012). Specifically, the pharmaceutical industry outsourcing refers to providing pharmaceutical companies with drug development, production and marketing services through the form of contracts. Usually, bio-pharmaceutical outsourcing is divided into three forms: Contract Research Organization (CRO), Contract Manufacturing Organization (CMO) and Contract Selling Organizations (CSO). To small firms, the pattern of outsourcing provide them with the opportunity to import technology and rapidly improve the ability of independent research and development. To large enterprises, the pattern of outsourcing can help them to reduce some of their R&D work and focus on core technical work, thus to lower their production and operating costs, and enhance their market competitiveness.

To build a diversified financing system for industrial development

The development of bio-pharmaceutical industry often requires huge capital investment; the intensity of capital investment may directly affect the development pace of biomedical industry. Therefore, in order to support the healthy development of bio-pharmaceutical industry, a diversified financing system should be established. China ought to make full use of multiple funding channels, including banking credit, venture capital, government financial support, foreign investment and stock markets, thus to raise funds needed by the bio-medicine industry. In particular, as research and development of new drugs is difficult and often long cycle, and faced with technical, clinical, marketing, and patent risks, it is urgent to improve the venture capital mechanism for bio-pharmaceutical industry.

To strengthen the intellectual property protection

In order to promote better development of China's biomedicine industry, it is necessary to speed up the

establishment of an active strategy for pharmaceutical intellectual property protection, and raise the level of the industry-wide awareness of intellectual property protection. Laws and regulations related to intellectual property protection of the biomedical industry should be improved, and the punishment for infringements should be increased, so as to create a good atmosphere for innovation among bio-pharmaceutical companies. Overall, the patent system should be used as an important mechanism to encourage innovation and boost technological innovation capability.

CONCLUSION

Biomedical industry may bring significant social benefits as for the national health, and also contains huge potential economic benefits. At present, the biomedical industry has become the focus of the strategy for economic and social development in countries of the world; many multinational companies are willing to invest more heavily in competing for the commanding heights of the international bio-pharmaceutical market. The development of bio-pharmaceutical industry is, to a large extent, dependent on technology, capital and human resource inputs, and requires a global market to share innovation costs. Therefore, international cooperation will be an important way to the development of this industry. China has a certain industrial foundation and huge market demands as for the development of biomedical industry. To accelerate the industry's development in the future, China should take advantage of the opportunities of globalization, give full play to resources and market advantages and widely participate in international cooperation and division of labor.

REFERENCES

- Baeyens K, Vanacker T and Manigart S (2006). Venture capitalists' selection process: The case of biotechnology proposals. *Int. J. Tech. Management*, **2**: 28-46.
- Chen L and Hung C (2010). An integrated fuzzy approach for the selection of outsourcing manufacturing partners in pharmaceutical R&D. *Int. J. Production Res.*, **24**: 7483-7506.
- Li X (2012). The rapid rise of Singapore's biomedical industry and its enlightenment to China. *J. Beijing Electric Power College*, **8**: 176-177.
- Ling L (2012). Rational evaluation of China's health reform for three years. *Health Economics Res.*, **5**: 7-12.
- Liu J (2012). China's biomedical industry survey. *Chinese & Foreign Corporate Culture*, **12**: 22-23.
- Lowman M, Trott P, Hoecht A and Sellam Z (2012). Innovation risks of outsourcing in pharmaceutical new product development. *Technovation*, **2**: 99-109.
- Nickisch K, Greuel J and Bode-Greuel K (2009). How can pharmaceutical and biotechnology companies maintain a high profitability? *J. Commercial Biotechnol.*, **15**: 309-323.
- Niu X, Zhu R and Zi L (2012). A comparative study on optimum development mode of bio-pharmaceutical industry. *Inquiry into Economic Issues*, **2**: 49-53.
- Sheng G and Shao Y (2012). The development situation of and countermeasures for biomedical industry in Tianjin. *Tianjin Science & Technology*, **6**: 67-69.
- Wang S and Chen Y (2012). Current development situation of biological medicine industrial parks and countermeasures in China. *Chinese Pharm. Affairs*, **10**: 1048-1051.
- Xu G and Chen F (2012). China's biomedical industry development status and strategies. *J. Clin. Hepatology*, **5**: 478-480.
- Zhang Y, Liu Y and Wang X (2012). Research on open innovation of China's bio-pharmaceutical industry. *Modern Business Trade Industry*, **14**: 1-2.
- Zhu L and Feng G (2012). U.S. bio-pharmaceutical industry policy and its enlightenment to China. *Chinese J. Pharm. Tech. Economics and Management*, **1**: 86-89.