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SCP Analysis of Biopharmaceutical Industry in China

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ABSTRACT

With the analysis paradigm of "structure-conduct-performance (SCP)" described in modern industrial organization theory, this paper analyzed the market structure, enterprise conduct and performance of biological pharmaceutical industry in China. It is suggested that the government to speed up the industrial restructuring, to optimize the industrial structure, to encourage the similar innovation, to optimize approval procedures of biological generics, etc.

Key words: bio-pharmaceutical; structure-conduct-performance (SCP); market structure; enterprise conduct; industry performance

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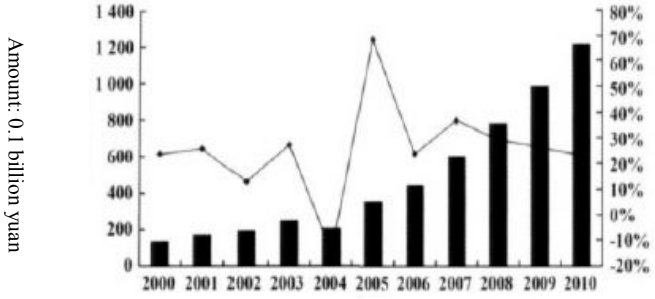
INTRODUCTION

As one of "strategic emerging industries", bio-pharmaceutical is mainly developed during "the 12th five year". It can promote the development of disease prevention technology and pharmaceutical health care products reduce the cost of national guarantee for national health and improve social welfare level. It is featured by intensive knowledge and technology, less-consumption material resources, great growth potential and good comprehensive profits. In addition, it plays an important role in realizing economic growth transforming from resources-driving to innovation-driving method. This paper applied industrial economic theory and combined bio-pharmaceutical actual data in detailed analysis for market structure, enterprise conduct and industry performance of bio-pharmaceutical in China in recent years according to the framework of structure-conduct-performance (SCP).

1. market structure of bio-pharmaceutical industry (S)

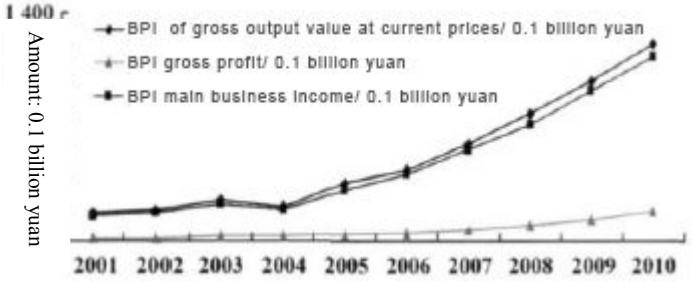
1.1 Industry scope

Since reform and opening-up, Chinese pharmaceutical industry obtained rapid development, gross output value increased from 7.9 billion yuan in 1978 to 1174.13 billion yuan in 2010, including 120.8 billion yuan gross industrial output value of bio-medicines and bio-chemical medicines, 10.29% of gross output value of the medical industry. Although its output value proportion is lower than that of chemical medicines and traditional Chinese medicines, it is the very department with the fastest development in the pharmaceutical industry, during 2000~2010, annual average compound growth rate of total output value of bio-pharmaceutical industry was up to 24.45% (referring to Fig. 1). Main operation income was increased from 14.82 billion yuan in 2001 to 112.87 billion yuan in 2011, total profits increased from 1.92 billion yuan in 2001 to 17.85 billion yuan in 2011 (referring to Fig. 2). Our export delivery value of bio-pharmaceutical industry is increasing stably. Export delivery value of our biological and bio-chemical manufacturing industry was up to 19.018 billion yuan in 2011, an increase of 20.36% year-on-year[1], indicating the stable increasing trend of our bio-pharmaceutical industry (BPI) scale.



Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2001-2011).

Fig. 1: Gross output value and increase year-on-year of China BPI during 2001-2010



Data source: Cleansed according to *China Statistics Yearbook on High Technology Industry* (2001-2011).

Fig. 2: Gross output value, main business income and gross profit of China BPI during 2001-2010

1.2 Market concentration rate

Generally speaking, absolute concentration rate CRn is the index mostly applied to measure market concentration rate. CRn refers to the share (%) in the total industry of output and sales amount of the first top n enterprises with the large scale in a specific industry. It is very easy to determine absolute concentration rate. CRn can reflect industry concentration condition with good accuracy and indicate market monopoly and competition degree. It can be calculated according to the following equation:

$$CRn = \sum_{i=1}^{n} Xi / \sum_{i=1}^{N} Xi$$

China BPI market concentration rate was increasingly increasing in recent years; CR4 and CR10 of BPI were 7.03% and 10.70% respectively in 2009 and increased to 8.47% and 13.43% in 2010 respectively. American economist Bain was the first man to use absolute concentration rate index in classification study of industry monopoly and competition degree. He divided the concentration type into six grades according to CR4 and CR10. It is known according to Bain's classification method that market structure of China BPI belongs to the atom-type scattered competition with low concentration rate and immature industry development.

The reason mainly is promotion of policy that China encourages the development of biology industry, lots of new bio-pharmaceutical enterprises (BPEs) are established; Moreover, a great many chemical pharmaceutical and traditional Chinese medical enterprises have transferred their investment to bio- pharmaceutical business in recent years, which has scattered industry resources, have made market concentration rate lower than that of developed countries as well as that of other domestic industries like chemical medicine and traditional Chinese medicine (CR10 of medical industry was 38.64% in 2009). Due to the leading enterprises in the industry have entered into the rapid development stage, with enterprise technology and scale advantages appealing gradually, market concentration rate of bio-pharmaceutical markets (BPM) have been promoted at a speed higher than other departments of pharmaceutical industries.

1.3 Market entry and exit barriers

New enterprises entering the industry may complete with the existing enterprises and may meet very bad factors and the obstacles restricting the new enterprises entering the industry compared to the existing enterprises, such factors and obstacles are called as entry barriers. The corresponding exit barriers refer to the obstacles during the enterprises

quit the market or cut the original business. As to BPI, market barriers mainly include scale economy barrier, product differentiation barrier, technology barrier and policy and regulatory barrier, etc.

1.3.1 Scale economy barrier

So called scale economy refers to cost per unit of an enterprise decreasing with increasing production scale. According to the classification standard of scale economy barrier degree by Japanese famous economist Masu Uekusa, scale market proportion (d) = the optimal scale (S/N) / market scale (S) = 1/N, where, S refers to gross output and N refers to the enterprise number [2]. For a total of 862 BPEs in China of 2010, then d = 1/862 = 0.1160%, d < 5%, so China BPI belongs to a low-scale economy-barrier industry, basically without scale economy barrier.

We can use average output indicator to interpret the scale economy barriers, namely higher average output, higher entry barriers. It's indicated by studies and practices at home and abroad that medical industry is an industry with significant scale economy and huge minimum enterprise scale (MES) enterprises taking more market shares. Being affected by scale economy barrier, mature pharmaceutical markets in E.U., U.S.A. and Japan etc. have formed monopolized market structure presently [3]. Average output value scale of China BPI kept increasing during 2001-2010 (referring to Table 1), but compared to the developed countries, it shall be of small scale with weak scale economy. Thus, it is good for creation and development of small and medium-scale BPEs. The small and medium-scale enterprises are the major part of the industry, and the large-scale enterprises take up a low market share. Gross assets of the large-scale enterprises in China BPI only took up 5.51%, while the one of small and medium-scale enterprises took up 52.01% and 42.48% in 2011.

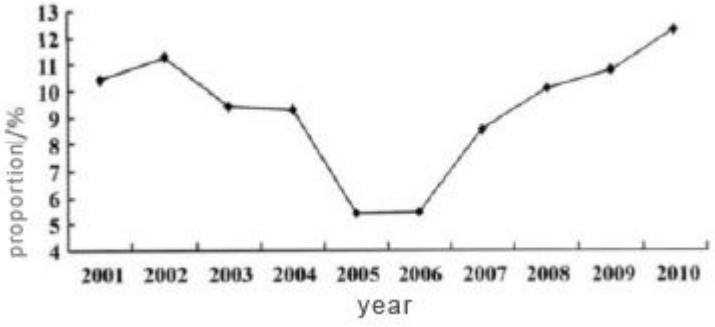
Table 1: Average output value scale of China BPI during 2001-2010 0.1 billion yuan

Year	2001	2002	2003	2004	2005
Average output value	0.56	0.57	0.70	0.48	0.73
Year	2006	2007	2008	2009	2010
Average output value	0.83	0.97	1.04	1.20	1.40

Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2001-2011).

1.3.2 Product differentiation barrier

Product differentiation barrier refers to product entry barrier resulted from product differentiation. The existing enterprises are advantageous in product quality, marketing orientation and enterprise image and other aspects, while the new enterprises must pay more to make their own products accepted in the market, which increases the cost of new enterprises and makes the product differentiation an entry barrier of the industry. Product differentiation is hard to described only with a specific indicators, so this paper give a rough description with the proportion of new biology and bio-chemical products' sales income in the main business income of BPEs. Seen from the statistics in Fig. 3, new products' income in China pharmaceutical industry took a decreasing proportion during 2005-2006 and showed an increasing trend, but the increase level in 2010 equal to the increase level in 2001. Over 95% bio-pharmaceutical products are the similar products, production capacity of some low-end products are excessive, with bad idle resources and waste. Compared to European and American market mainly engaged in patent medicines, the China BPI products get a very low product differentiation barrier in a whole.



Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2001-2011)

Fig. 3: New BPI products' income proportion in main business income of the enterprise etc.

1.3.3 Technology barrier

BPI is featured by difficult research & development and production technology, high demands for devices, complex processing routes and very strict production environment requirements. To study and develop a new drug or a similar drug generally takes about a decade with higher demands for comprehensive qualities of the researchers including technological level and experience accumulation.

As a matter of fact, most China BPEs still compete with the similar products. Bio-similar products are different from the common chemical similar products, for bio-similar products (including products for therapy or prevention) are featured by heavy molecular weight and complex structure, added by limitation of the current analysis method, product quality, especially its biology reactivity is trend to be affected by various factors and become unstable, and production technique is so complex and hard to copy thoroughly, so the bio-similar products must be produced after a all-round comparative study on the listed original bio-products, including quality, non-clinic and clinic test, etc., so as to ensure the safety and effectiveness. According to *Drug Registration Regulation* issued by China Food and Drug Administration in 2007, no matter the original new drug or the similar drug, biology drugs must be registered according to the procedure for application of a new drug. Therefore, as for manufacturers of bio-similar products, research cost and circle have been increased before being listed of the drug and technology barrier of bio-similar products is higher than chemical medicines and traditional Chinese medicines [4]. Development of a biology product must include "upstream development" spanning research & development in lab and trial production in a small quantity, as well as "downstream project" spanning mass production in workshop and market promotion. Furthermore, "downstream project" of biotechnology industrialization is much more important than "upstream development". Experts believe that research technology of China BPI upstream is 5 years behind foreign countries, downstream application and development technology 15 years behind at least [5]. Chinese products mostly focus on low-end similar vaccines and blood products industry with low technology barrier.

1.3.4 Policy and regulatory barrier

China constitutes a series of laws and regulations, including Drug Administration Law, Regulation on Drug Manufacturing Enterprise Management and Interim Provisions Concerning Establishment of Drug Manufacturing Enterprise, in terms of pharmaceutical industry entry, production and operation, etc. Moreover, the new enterprises shall meet the demands for product lot number and the workshop must meet the demands specified in *Good Manufacturing Practice* (GMP) and other demands. Presently, China carries out license system for drug production and operation. Requirements for being listed of the products of drug enterprises and products quality standard shall be lower than that in the developed countries. China lists biology industry into "strategic merging industries" mainly developed during "the 12th five years", and give great policy support and tax preference at various aspects for establishment of BPEs.

Patent protection policy is very important for BPI with high innovation. State Intellectual Property Office of the P.R.C. shall transact and appraise the patent application. The office shall take action according to *Patent Law* if any infringement. However, it takes a long time to appraise the patent application in China, and "earlier disclosure and deferred examination" system is time-and-energy-consuming for the patentees, and which lastly turns out rejection for the patent application, and accordingly makes technology secretes of the applicants fully open without any effective protection and make their economic benefits damaged. In addition, our *Patent Law* takes no consideration of early research and development of the new drug and the consumption problems of patent validity resulted from the appraisal, as a matter of fact, the patentees get less validity time for the patent benefit. We shall learn from U.S.A., Japan and other countries' related good experiences, optimize policy and regulatory barrier and promote the development of BPI [6].

2. Analysis on Chinese BPI market and enterprise conduct features (C)

2.1 Research & development conduct

Statistics indicate that, during "the 11th five years", total investment by China BPEs took less than 3% total income, and investment on research and development of key pharmaceutical enterprises took about 5% total income (refer to Table 2). During "the 12th five years", the Ministry of Finance of the P.R.C. launched the capitals for "special manufacturing of significant new drugs" increased from 26.6 billion yuan to 40 billion yuan, the unprecedented investment, which indicated urgent demands for independent- researched new drugs in the industry. Compared with the other countries, top 10 international leading pharmaceutical enterprises for research and development invested a total of 60.24 billion yuan as funds for research and development, nearly 10 times of capitals for manufacturing significant new drugs in the following five years of China, among which, Japan Takeda Pharmaceutical Co., Ltd. invested the most sales income, 29.5%, a total of U>S. 4.64 billion dollars.

Investment on research and development of Chinese pharmaceutical enterprises is far behind the developed countries for the following reasons: Firstly, rising cost and "low-price tendering" result in the decrease of the medicine prices, thus the enterprises' economic benefits have been reduced under double pressure, with enlarged lose scope and direct reduction of investment on research and development of the enterprises. Secondly, the financing system is unsound and enterprise financing is difficult. Annual reports issued by bio-pharmaceutical listed companies during 2008~2010 indicate that self-financing of the enterprises holds 71.8% funds financed for research and development of the enterprises, governmental investment 13.4%, others like loan from financial institutions 4.8% [7]. Besides of enterprises' self-financing and governmental investment, the enterprises get little funds from

other channels, so it is hard to financing for the enterprises. Thirdly, Chinese BPEs have drawback consciousness on research and development. The process of research and development of new medicines still adopt academic methods, starting from bibliography, actually on the me-too way, lacking originality. Research and development cost is low, in fact, the same investment on research and development could obtain a higher return. A great many enterprise start to introduce international cooperative projects in patent license, sharing interests and rights and other methods, actively explore various international cooperative modes so as to improve internationalized research and development capacities and avoid research and development risks.

Table 2: Investment on research and development of key Chinese pharmaceutical enterprises in 2009

Company	R&D Investment/ 10,000 yuan	R & D strength /%
Jiangsu Hengrui Medicine Co., Ltd.	8182	6.94
Zhejiang Huahai Pharmaceuticals Co., Ltd.	2009	4.75
Zhejiang Hisun Pharmaceutical Co., Ltd.	4923	2.25
Shanghai Huayuan Pharmaceutical Co., Ltd.	1824	2.07
Tianjin Tasly Pharmaceutical Co., Ltd.	2822	1.92
Shanxi Yabao Pharmaceutical Group	1.242	1.81
Shenzhen Accord Pharmaceutical Co., Ltd.	2.556	1.56
Average	3.365	3.0

Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2010)

2.2 Merger & cooperation conduct

Merger and cooperation in BPI is featured of typical "capitals and technology". Various start-up-type small and medium-size BPEs could not afford the expensive research and development investment and huge research and development risk for new medicines' research and development, and often are strapped by cash. In contrast, as for large size BPEs with certain capital advantages, relying on capital advantages for rapid integration of promising project type companies is a good way to expand. For example, Luye Pharma purchased 80% shares of Singapore biotechnology company A-Bio Pharma and started the overseas merger of Chinese BPEs in 2010. In addition, in order to avoid policy change, value evaluation, operation integration and other risks, BPEs often adopt joint projects or establishment of joint venture companies for cooperation, for which not only can reduce research and development risk of new drugs but also reduce capital pressure of the enterprises. Simcere Pharmaceutical Group established strategic cooperative relationship with American Advenchen Laboratory Co., Ltd., Epiomics Co., Ltd. and BMS Co., Ltd. for joint research and development of new anti-tumor drug AL6802 in 2007. Simcere Pharmaceutical Group signed cooperative framework agreement with MRK Co., Ltd. for establishment of joint venture enterprises in China in future.

Merger cooperation among enterprises can reduce procurement cost of the enterprises, fixed cost and labor cost per unit, average marketing cost, research and development fee per unit and other expenditures, but all of the above must be based on simultaneous growth of enterprise management capacity, otherwise never mention the effect of scale economy. Most merger conducts of the Chinese existing BPEs take no consideration of self ability and long-term development plan, only concerning on short-term interest. Merger parties with bad strategic matching may cause limited value potential resulted from merger [8]. Merger funds of Chinese BPEs mainly come from bank deposit with sole payment method. Once the government adopts tight monetary policy, rising bank interest rate will increase procurement cost and break down the enterprise merger capital chain. Moreover, Chinese BPEs mainly adopt horizontal merger, and seldom adopt vertical merger (merger the enterprise at the same industry chain with the enterprise). In fact, it is bad for improvement of core competitiveness of Chinese BPEs and development of BPI.

3. Chinese BPI performance

3.1 Profitability

Among indicators evaluating profitability, the three large indicators are earnings per share, return on assets and return on equity. Earnings per share are to divide net cash flow resulted from operation activities by the quantity of outstanding shares and reflect average cash flow obtained per share. Return on assets is the percentage showing how profitable a company's assets are in generating revenue and reflects profitability of the enterprises with various capitals. Return on equity is the rate of an enterprise's average net assets of net profits of the enterprise during a period and reflects the efficiency at generating profits from the shareholders' equity. These three indicators can reflect profitability and performance of the enterprise. We apply the data during 2009-2011 of 113 BPEs listed in Shanghai and Shenzhen exchange to analyze the profitability of Chinese BPI in recent years. Refer to Table 3 [10].

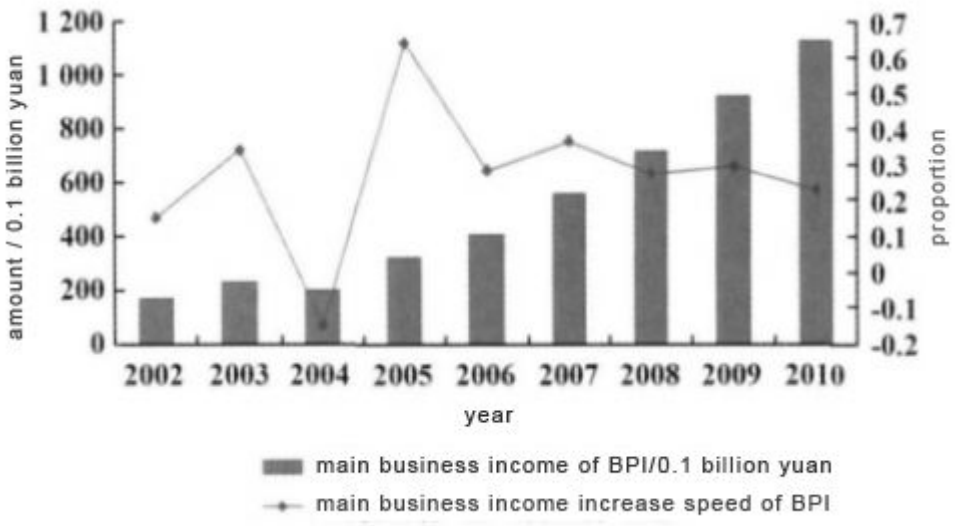
Table 3 Profitability indicators of BPEs during 2009-2011

Financial index	Year	Average	Max.	Min.	Std diff.
Earnings per share	2009	0.6067	2.98	-0.4343	0.6160
	2010	0.5863	3.08	-0.9	0.5607
	2011	0.5147	2.88	-1.17	0.5381
Return on assets	2009	13.8834	57.295	-14.0665	11.2776
	2010	11.1979	35.3714	-15.4486	7.7924
	2011	10.2578	39.9304	-17.1007	7.2677
Return on equity	2009	17.5990	96.3497	-35.5913	17.2301
	2010	13.9991	47.2027	-24.5597	10.4786
	2011	11.8058	37.1862	-39.633	9.4753

Seen in a whole, earnings per share of Chinese BPEs was between 5%~6% during 2009-2011, and return on assets and return on equity between 10%~20%. It indicated that profitability of BPI is good compared with other industries. However, the three indicators were reduced gradually during 2009-2011. In fact, since 2009, BPI profit increase maintained the lower level in the history, mainly resulted from reinforced governmental control on drug prices. National Development and Reform Commission carried out "administrative down regulation" for the prices of some biological drugs in 2011, meanwhile, all the cities and districts promoted "low price competitive bidding" mode in provincial drug tendering procurement, which resulted in further increase of sales cost of BPEs. Price rising space of bio-drugs is blocked, higher gross profits cannot be maintained, and BPEs' pressure is enlarged. In addition, the difference between the maximum value and the minimum value is huge, so is standard difference. The large standard difference reflecting return on equity of profitability indicates the polarization existing in BPEs, but it is lucky that the difference becomes less and less year by year.

3.2 Growth Capacity

Most literatures adopt the growth rate of main business income of the industry to measure growth capacity of the industry. This paper also adopts this indicator, namely (main business income of BPI for that year-main business income of BPI for last year)/main business income of BPI for that year, to measure the growth capacity of BPI. It is referred to Fig. 4 that main business income of BPI was stably increasing, with an increase speed curvedly decreasing, in recent years.



Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2003-2011)

Fig. 4 Main business income and increase speed of BPI during 2002-2010

Chinese BPI scale keeps rapid expansion trend under stimulation of domestic quickening up development of BPI and other strategic emerging industries. But, issuing and carrying out of Pharmacopoeia of the People's Republic of China 2010 edition and new GMP regulations affected production and operation of BPEs and slowed down increase speed of industrial capital scale continuously.

3.3 Technology innovative ability

Seen from Table 4, patent application number and effective invention patent number of BPEs was increased rapidly since 2006. But actual enterprise profit and sales income was not increased rapidly, due to long circle for research and development of a new drug. It takes about 10 years from obtaining research and development patent to the products put into sales as listed products. Presently, besides traditional Chinese medicines, independent rate of

Chinese pharmaceutical products only shares 3% market with weak competitiveness and hard to enter into the international high-end market in European and America. Among the gene project drugs listed in China, besides of alb type interferon (IFN-alb) as the first international product, others are similar products or tracing products. The first reason is lack of innovative incentive mechanism for a long time in China, resulting in shortage of innovative spirit of most enterprises; secondly is the weak knowledge on intellectual property and patent system.

Table 4 Invention patent number of Chinese BPI during 2006-2010

Year	2006	2007	2008	2009	2010
Patent application No.	124	264	254	321	382
Effective patent No.	119	276	293	294	402

Data source: Cleansed according to China Statistics Yearbook on High Technology Industry (2003-2011)

Compared with U.S.A. and E.U. with higher-level bio-pharmaceutical application amount, Chinese bio-pharmaceutical application amount still be around the low level after breaking through zero record in 2003. The number of new drugs listed annually in U.S.A. surpasses 35 times of Chinese, because independent research and development rate of the products is very low, added by incomplete technology industry chain and disconnected production and research. "Downstream project" of biology industry chain is much more important than "development link" as mentioned above. China lacks "downstream project" link of "pilot, magnification and integration" and accordingly results in various technology accomplishment without industrialization.

4. Policy suggestions on development of Chinese BPI

Chinese BPI has obtained rapid development in recent years, but it is found from analysis under SCP framework that Chinese BPI has been of defects like low integration, small enterprise scale, small investment for research and development, incomplete industrialization of technology accomplishment, low product innovation degree and incomplete policy barrier, for which, the following suggestions are brought forward.

4.1 Encourage strategic merger, optimize industry structure

To realize strategic change from large pharmaceutical country to strong pharmaceutical country, it is inevitable to improve industry integration and form into industry pattern of great group and large pharmaceutical. China shall encourage BPEs with complete operation, good product structure, advanced production technology and strong market competitiveness to adopt merger, acquisition and procurement and other methods to merger the small-size BPEs with weak competitiveness and complementary advantages and issue related policies to support normal merger and vertical merger of the enterprises. On the other hand, the enterprises shall firstly consider their own conditions and future long-term planning as well as future operation strategies while mergers and acquisitions so as to avoid blind merger and acquisitions.

4.2 Broaden financing channels, increase research and development investment

It is known that bio-pharmaceutical industry is "the brightest industry" at the growth stage of industry life cycle with good profitability, attracting great interest of risk investment. It is believed by some scholars that introducing risk investment is a good way to development BPI and to solve shortage of research and development investment. The government is improving urgently the second board of high-tech industries with BPI as the leading industry and setting the lower entry barriers and the wider share issuing conditions. Furthermore, investment banks, insurance companies, endowment funds and bank holding companies as well as families and individuals with investment intention and others can put their attention to increasingly developing BPI with great earnings.

4.3 Focus on infrastructure research, promote transformation of technology achievements

The government shall increase investment on scientific research infrastructure construction, form into several life-scientific-research bases at international advanced level and strengthen BPI innovative infrastructure research capacity and engineer development capacity. Shall make full use and strengthen the existing bio-pharmaceutical technology resources and form into a scientific research agglomeration integrating bio-pharmaceutical application foundation research, application research and development research, based on which the government has established a technical support platform with good scientific achievement demonstration, technical service, consultation and research incubation function so as to realize resources integration, equipment share, cost reduction and promotion of sustainable development of BPI; Shall actively guide and encourage the enterprises to increase research and development investment, promote bio-pharmaceutical technological innovation system with the enterprises as main body and enterprise-university-research combination. Support innovation capacity construction of the advantageous enterprises and establishment of technical center of the enterprises, meanwhile, promote specialization service construction related to BPI development and promote establishment of authorized agents, as well, transact new drug application, patent application, information consultation, technical exchange and special trainings, etc.

4.4 Encourage development of imitative innovation, obtain independent intellectual property rights

As to creation of new biology drugs, imitative innovation is different from imitative drugs totally copying other drugs' chemical structure, instead, based on the existing patent drugs, modify and reform the chemical structures of the known drugs' structure as the leading compound and make independent patent drug through systematic pre-clinical and clinical researches. Meanwhile, this method ignores the process of pathogenesis and drug targets finding, for there is pharmacological evaluation system to learn from, so it is of strong purpose, less investment, shorter circle and higher success rate, and can get independent intellectual property rights. Therefore, as for the actual condition of Chinese BPEs with weak technical level and shorting research and development capitals, imitative innovation is the best new mode. Chinese BPEs shall make full use domestic scientific research advantages like cheap but good Chinese scientific talents, scientific research foundation in some fields and abundant and unique disease sources. Chinese BPEs shall learn from development experience of Japanese and Indian BPIs, pay attention to research information of new drugs, and keep upgrading and improving technologies introduced so as to derive the dependent patents stamped with Chinese characteristics from basic patents of other countries. We shall fuse our own advantages and get independent intellectual property rights from imitative innovation.

4.5 Optimize bio-pharmaceutical approval procedure

Drug Registration Regulation has taken research and development cost and circle before being listed and sold of the drugs of biology imitative drug enterprises into consideration in terms of regulation of application procedure of biology imitative drugs according to new drug application. The author thinks that China Food and Drug Administration shall focus on simplifying approval procedure, making corresponding technical guide principle, shortening approval time and other aspects under the precondition of fixing bio-imitative pharmaceutical scope, and make regulations or supplements for the original regulations, technical guide, technology and quality standard and pharmaceutical market principle including procedures and systems. China can confer approval bio-imitative drugs system in U.S.A. and E.U. in terms of registration management, standardization and quality control of bio-imitative drugs so as to perfect the related regulations and laws.

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