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Research Report of Chinese Off-patent Drug Market, 2009

https://marketpublishers.com/r/RA9394B507AEN.html
Date: April 2009
Pages: 50
Price: US$ 1,368.00 (Single User License)
ID: RA9394B507AEN

Abstracts

The off-patent drugs refer to a kind of copy drug, which have the same dosage, security, strength, quality, performance and intended uses to the commercial name drugs. The legal acquirement of the off-patent drugs approximately concludes two situations: one is the pharmaceutical copy after the patent expiration; the other is the government obtains the production of the off-patent drugs by means of compulsory license in the field of patent drugs relate to the public health.

As the gradual reduction in the approved patent drugs in the market in the world, the development pace of the potent drugs is restrained. The patent expiration of a group of blockbuster pharmaceuticals is just in the corner. The potent of the original researched drugs at market value of 24 billion USD will become invalid in 3 to 5 years. In the next 5 to 10 years, the global off-patent market will usher the overdue pharmaceutical patent business opportunities at the market values of 120 to 150 billion USD, which will bring great business opportunities for the development of the off-patent drugs.

Besides, with the gradual growth of the off-patent drug market, the multinational pharmaceutical giants, such as Pfizer, Sanofi-Aventis and Bayer etc, will involve in the off-patent drug industry.

The off-patent drugs will play important role in the future pharmaceutical market.

At present, the scale of Chinese off-patent drug market is about 80 billion Yuan, which still has huge development space in the future. According to the analysis by the experts, the off-patent drugs and the patent drugs are expected to occupy 70% and 30% of the market shares respectively in 5 to 10 years. By 2012, China will become the second largest off-patent drug market in the world at the compound growth rate of 14%.

Although China had carried out the compulsory GMP authentication from 2004, Chinese domestic pharmaceutical manufacturers did not cut down but rise, which had been developed from 3,731 in 2004 to over 4,000 at present. Because Chinese pharmaceutical enterprises are characterized as sparse, random and small, the new drug innovation is in the very beginning phase and most enterprises do not have the capacity of creating new drugs and the proportion of the investments in the new drug research is less than 3%. At present, Chinese local enterprises have brand influences and strong competitiveness; the top pharmaceutical enterprises in large scale are all specialized in the off-patent drug business.

At present, China has more than 4 thousand pharmaceutical enterprises, over 80% of which are the medium and small enterprises. However, America only has about 200 pharmaceutical enterprises. Due to the limited research level, Chinese pharmaceutical enterprises are mainly engaged in the production of the off-patent drugs and the independent renovative pharmaceuticals only account for a small part. Many pharmaceutical enterprises involve in the off-patent drug market, resulting in the fierce industry competitions. Compared with the developed countries, such as America, there is big gap between the production and sales of Chinese off-patent drugs. The average profit is only about 5 to 10 percent in Chinese off-patent drug industry, which reaches 40 to 60 percent in the globe. Among Chinese local pharmaceutical enterprises, there is almost no outstanding enterprise, which even lacks the international market experiences.

From October 2007, China began to carry out the new Drug Registration Regulation. According to the new definition of new drug in Drug Registration Regulation, the scope of the new drugs is narrowed down. Only the real new drugs can receive the new drug certification. The application of the drugs comforting to the previous national drug standards is called the off-patent drugs. In the previous time, the simple reformed drugs could also receive the new drug certification, which are not qualified to receive the new drug certification in the new regulations. Although China examines and approves numerous drug applications, only a small part is the creative drugs. The original definition of the new drugs is the drugs which had not been in the market before and some only made some changes, leading to the serious situation of one drug with many names.

The phenomenon that the off-patent enterprises are knocked out the market conforms to the laws of the market. If the enterprises do not enable to cater to the new management measures, it is certain and inevitable to knock out the market, which is

also the law of the market.

Chinese new medical reform plans will intensify the government investments in the medical security; construct the basic residential medical systems covering the urban and rural areas, which will be good news for the advantageous off-patent drug manufacturers after the fiercest competition.

From the aspect of the present situation, there are two merits for Chinese domestic pharmaceutical enterprises to take participate in the international off-patent drug competition: first, the comparative low production costs-the labor force costs less; China is abundant in raw material resources. Meanwhile, the costs for the environmental protection are also very low; besides, most pharmaceutical enterprises in China are engaged in the production of the off-patent drugs and have high copy capacity. At present, Chinese off-patent drug enterprises can make the most uses of the copy ability to obtain the competition advantages through getting the pharmaceutical information of the expired drugs.

Meanwhile, there are three aspects restrained Chinese domestic pharmaceutical enterprises from competing in the global market: first, the comparative low quality of the off-patent drugs and placing the unfavorable position compared with the developed countries; second, the inferior research environments and abilities compared with the developed countries. The off-patent drugs have high requirements on the technologies, which will restrain the capacity of Chinese off-patent enterprises; third, the largest demerit of Chinese pharmaceutical enterprises is the insufficient in investigating the global market and not familiar with the situation of the global pharmaceutical market, which is caused by the language and cultural differences as well as the shortage of the international market experiences and insufficient investments in the international pharmaceuticals.

Like the patent dug market, the foreign enterprises gradually enter Chinese off-patent drug market. Chinese off-patent drug market will face various challenges, not only their own transition, but also more and more foreign funded off-patent drug competitors.

When the international financial crisis sweeps the globe and various industries are in depression, Chinese pharmaceutical market has attracted attentions from domestic and oversea investors. Due to the special features of the pharmaceutical industry and the rigid demands for the pharmaceuticals, Chinese off-patent drug industry is less affected by international financial crisis, because the major market of Chinese pharmaceutical enterprises concentrates in the domestic market.

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Most of the data in this report come from the first-hand investigations and meanwhile cite abundant second-hand information. This report mainly analyzes the development environments and present situation of Chinese off-patent drug market as well as the detailed analysis of the major global off-patent market. The related enterprises can learn some experiences and discover the potential investment trends and opportunities. This report is of high reference values to understand present development situation, competition patterns, the market trends and development trends of Chinese off-patent drug market so as to master the investment opportunities.

More following information can be obtained in this report:

- Present Situation of Chinese Off-patent Drug Market
- Development Environments of Chinese Off-patent Drug Industry
- Influences of International Financial Crisis on Chinese Off-patent Drug Industry
- Prediction on the Development Trends of Chinese Off-patent Drug Industry
- Major Enterprises and Their Operations of Chinese Off-patent Drug Industry
- Investment Opportunities of Chinese Off-patent Drug Market

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