Bluepharma – Entering the Chinese pharmaceutical market

Bluepharma is a Portuguese pharmaceutical company based in Coimbra, Portugal. At the end of 2010, the company paid its first visit to China. A year later, with the help of a Portuguese consultancy firm and a Chinese partner, Bluepharma is very close to obtaining the registration of their first product in China, which aims to be launched in the Chinese market by 2013.

Business: *Pharmaceutical manufacturer*
Number of employees: *232 worldwide*
Turnover: *EUR 22 million in 2010*
Target market in China: *Generic drugs*

Bluepharma

www.bluepharma.pt

Bluepharma was established in February 2001 in Portugal by a group of professionals who were connected with the pharmaceutical industry and bought a state-of-the-art industrial unit from the German giant Bayer. Today, the company has 232 workers and its main areas of activity are contract manufacturing, R&D and production and commercialisation of generic medicines, covering a large range of diseases (bone diseases, diabetes, cardiovascular diseases, digestive diseases, among others). Bluepharma is certified by the European Pharmaceutical Quality Standards, current Good Manufacture Practice (cGMP Certification), South Korean FDA and the USA Pharmaceutical Quality Standards from the Food and Drug Administration (FDA Certification).

Coming to China

Before coming to China, Bluepharma's only China experience was buying active pharmaceutical ingredients (API) in China through a German trader.

From December 13th to 17th 2010, Professor Sérgio Simões (Vice-President for Business and Product Development of Bluepharma) together with Dr Paulo Barradas (CEO of the company) visited China for the first time, with the support of a Portuguese consulting firm. They met registration agents, traders and manufacturers while starting negotiations. The company's current priority is to sell its drugs in the China market together with its Chinese partners. So far no physical office has been set up in China.

Before coming to China, Bluepharma already had a presence in Europe, the US and Australia, with some business links in Russia, Africa, the Middle East and Asia. Being the second largest economy in the world, the Chinese market is an opportunity for Bluepharma. "The pharmaceutical market in China is huge compared to Europe, and it is growing much faster," Professor Simões said.

Two objectives to be achieved in China:
1. To identify a partner capable of registering their medicines.
2. To select a partner that can distribute the medicines.

Bluepharma has been looking at China for a while and had a clear idea of what it was looking for: the company needed a Chinese partner to help with the drug registration and other partners for distributing its products in China. "Because the local players have very competitive prices, the market we are looking for is not too price sensitive, but niche products that can be differentiated from the others," Professor Simões stated.

With the assistance from a Portuguese consultancy firm which has offices in China, Bluepharma developed an entry strategy in order to approach the Chinese market. Their goal was to better understand the Chinese pharmaceutical market by studying Beijing and Shanghai as well as to identify potential Chinese business partners for distribution and R&D.

Bluepharma used the following criteria for selecting potential partners:

- Location: Based around Beijing and Shanghai;
- Type:
    - Registration agents;
    - Pharmaceutical manufacturers;
    - Pharmaceutical trading companies.
- Experience:
    - More than five years' experience in the pharmaceutical industry;
    - Previous experience in cooperation with European and American companies;
    - Good connections with local authorities.
- Other criteria:
    - Intention for long-term cooperation;
    - Good creditability and reputation in China.

Bluepharma's first visit to China was an important step as it enabled them to gain deeper market knowledge particularly on the entry barriers, the main players in the industry, the value chain in China and the regulatory requirements for the market. Local distributors also helped

Bluepharma understand the distribution process, the type of medicines most likely to be successful, the differentiation elements from existing products in the market, and other key success factors.

Product registration

To export medicines to China, it is important to understand the process for product registration. "The registration process in China is different from that in other countries. There are many relevant regulations and you need to know all the details. My advice is that companies have to find a local partner in China with significant expertise," Professor Simões said.

The import and sales of drugs in China must be carried out under national laws and regulations on pharmaceutical management. Therefore, even with products already approved in Europe and in the United States, companies still need to conduct clinical trials in China.

Only after obtaining the Import Drug Certificate from the SFDA (State Food and Drug Administration), the products can be imported by a Chinese partner that holds a Drug Supply Certificate. The importer is required to make an import record at the government agency for the imported drugs. Afterwards, the Chinese partner (importer or distributor) can sell the products to local drug agents or to the final customers, such as hospitals, clinics and drug stores, directly.

So far, Bluepharma has submitted only one product registration application through its Chinese partner in China.
Approval is expected within a year. Bluepharma is currently trying to register other products. For this purpose, the company is in close contact with a Chinese partner to help identify the right partners.

The costs associated with the product registration in China can be divided into three types:
1. Government authority charges: the fee charged by the SFDA is around CNY 45,300 (EUR 5,656)[1] for each application. The inspection fee will be decided by the Customs Inspection Centre.
2. Bioequivalence study[2] charge (required for Bluepharma's products and administered by SFDA): this part of the expenses depends on the products and the organisations that carry out the study.
3. Service fee: translation, consulting service, maintenance of relationship with authorities.

Although depending on the drug type, the clinical trial process in China generally takes at least six months.

[1] Bank of China Foreign Exchange Rate, July 4th, 2012.

[2] A bioequivalence study compares the bioavailability between a test and a reference drug product in terms of the rate and extent of drug absorption. Most nations require manufacturers of to-be-marketed generic drugs to prove their formulation exhibits bioequivalence to the innovator/patented brand products.

Distribution channels

Bluepharma concluded that, as with the process of registration of products, partnerships with local companies were needed to distribute its medicines in China. The local distributor should have a strong marketing team and a good network of contacts. "You need a local distributor with the marketing teams and all the connections already available for you. One partner is not enough because the market is so big - one for Beijing, one for Shanghai, eventually others for other provinces," Professor Simões stated. Bluepharma currently prioritises first tier cities rather than the second and third tiers.

During its trade mission to China, local distributors helped Bluepharma to identify market opportunities, among them generic drugs, identical to the original branded drugs whose patents have recently expired were highlighted, due to their clinical features, lower prices than the original branded drugs, and fewer domestic competitors. These generic drugs could easily be accepted by the public and prescribed by doctors. In addition, innovative products which can be differentiated from the existing ones also have good market potential.

So far, Bluepharma has signed agreements with a company in mainland China and a distributor operating in Hong Kong. Confidentiality, intellectual property, exclusivity and jurisdiction are the main clauses to look out for. "Approval of one of our products is almost granted, and this product should be in the Chinese market in 2013. We believe that China will become a very important market for our company," Professor Simões added.

Challenges

Identification of potential partners

Despite a growing Western influence, the Chinese market still has its own characteristics. For a foreign company like Bluepharma that comes to China for the first time, understanding the market clearly and identifying Chinese partners who are trustworthy are the key starting points.

High costs of product registration

For IPR protection, Bluepharma signed non-disclosure agreements (NDA) with Chinese companies at the very beginning of their cooperation.

The main challenge that Bluepharma is facing in China is the registration of the products. The Chinese pharmaceutical market is very strict and

there are very specific requests. For instance, Chinese authorities ask European companies to conduct lengthy clinical trials, causing additional high costs for the company.

Negotiations

To have access to the distribution channels, it is crucial to have a local player with an existing sales network. Chinese partners want to manufacture the foreign company's products in China. After hard negotiation, Bluepharma convinced the Chinese partner that they would manufacture in Europe but would use Chinese raw materials, as long as quality standards were guaranteed. Bluepharma believes that supplying China with medicines manufactured in Europe can be a key differentiating factor and it is important to protect IPR and maintain good control over the business.

Communication difficulties

One of the main challenges when negotiating with Chinese partners is the language. Even in big cities, it is still very hard to communicate in English and one should not underestimate this barrier. This barrier may affect the establishment of a cooperation or relationship to a large extent.

Relationship building

Good relationships ("Guanxi" in Chinese) with Chinese partners is a key success factor in China. It is a prerequisite for concluding business deals in China. Developing and nurturing Guanxi can be time consuming and resource intensive. It is more important than having a written agreement. Bluepharma understood the need to have frequent contacts with Chinese partners and long-term investment in building and maintaining these relationships, which are based on mutual trust, respect, humility, and reciprocity.

Best practice

1. Go to China on a regular basis. You need to be there as often as you can in order to maintain relationships with your partners and to keep abreast of the market.
2. Have someone who can help you with the local contacts and support you in the identification of the partners. A consulting company with experience in the Chinese market can give you the right support.
3. Identify partners in different regions of China. The market is huge, so do not target only Shanghai.
4. Sign a non-disclosure agreement with Chinese companies at the very beginning of cooperation.
5. Be patient. It is more important to develop a strong relationship with the partners than to have a written agreement, which takes time and perseverance.
6. Have at least one person from your staff entirely dedicated to the internationalisation process to China. If expanding to this market is a priority, one should allocate good resources.

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