

## BEST STRATEGIES WORKING WITH CHINA

programs such as medicinal chemistry, pharmacology, toxicology, biotechnology, biomedical engineering, etc. Students graduated from these universities in recent 5-10 years have a great deal of exposure to the most frontier research in drug discovery, development and manufacturing. They therefore gained good experiences and skills in these fields and can play important roles in both R&D and manufacturing if used appropriately.

### 4.5.3 How to tap low-cost labor

#### a. Establishing a wholly owned facility

Western companies can independently open an R&D center or a manufacturing facility in China and hire local scientists and technicians. But in almost all cases the Western company still needs to send their own management team to China to manage the operation on a daily basis, whether it is R&D or production.

#### b. Forming a joint venture (JV)

Western companies can identify a local Chinese pharma company that is able to make drug products, either APIs or intermediates. Then transfer the production technology to the JV and train local workers. Eventually let the local people manage the production and facility.

#### c. Establishing a partnership

As entire Chinese pharmaceutical industry has grown dramatically, Western companies now can have more choices, either to select an R&D oriented Chinese pharma/biotech company to co-develop novel drugs in China (such as the collaboration between Eli Lilly and Hutchison MediPharma) or to partner with a Chinese pharma company to manufacture APIs in China for their marketed drugs (such as the partnership between Pfizer and three Chinese pharma companies).

#### d. Outsourcing (or contracting out)

Western companies can outsource any part of their operations to China, either R&D or manufacturing. Literally, any part of a pharma/biotech company's operation can be outsourced as long as they can identify a service provider in China that can handle the outsourced projects. This will be the most feasible model in China at present time and suitable to any sized companies, large or small.

#### e. Sourcing low-cost chemicals in China

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At present China has a total of more than twenty thousand chemical companies, pharmaceutical companies or any other chemistry-related companies nationwide. They are producing hundreds of thousands of chemicals in various quantities, all in low price. These chemicals, some even rare ones, are at least 3-5 times cheaper than those provided by any countries in the West. As long as their quality meets desired specifications, these are definitely the best sources for Western companies to reduce cost and maximize profit margins.

In short, following features can best describe the current situation of Chinese-made pharmaceutical intermediates and APIs:

- Lowest price
- Most abundant
- Most complete inventories
- Most flexible orders

### **4.6 Advantages and disadvantages of each strategy for entering Chinese market**

#### **4.6.1 Marketing pharmaceutical products in China**

Chinese pharmaceutical market is currently still in its growing stage, not fully developed yet. There are still many issues waiting to be addressed and corrected. Participation of experienced Western pharma companies in developing this Chinese pharmaceutical market will be certainly welcomed by both Chinese patients and government. It also certainly presents great opportunities to these Western pharma/biotech companies to display their expertise and at the same time to benefit them from this huge market.

#### **Who can go to China**

At present time the Chinese pharmaceutical market is best suitable to those pharma/biotech companies who have approved drugs on market and want to expand their market in order to increase their sales revenue and/or offset their declining revenues in the West. All drug products in such categories as cardiovascular drugs (especially anti-hypertension and cholesterol lowering drugs), diabetes drugs, cancer drugs (especially those novel, mechanism-based drugs although at present their high price is a concern to many Chinese cancer patients), and COPD drugs are extremely welcome in Chinese pharmaceutical market. This approach is, however, not suitable to those small companies whose major activities are R&D.

#### **Challenges:**

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There are still hurdles to Western companies entering the Chinese pharmaceutical market. They include:

- a. Drug distribution system is still not fully developed. Presently, hospital pharmacy stores are still the major drug distributors in every city and county. Although the Chinese government has been determined to change the situation (such as encouraging more OTC drugs and online purchase), it would take at least several years to completely change the situation.
- b. Insurance and healthcare system is also not well established yet. Government just passed the regulations to require that every employer must provide health insurance to every employee of theirs. However, a large number of Chinese, in particular those in rural areas, still do not have health insurance. Although government has now provided basic insurance coverage to them, they are not able to afford expensive Western medicines.
- c. Drug advertising to educate ordinary Chinese people is still not as popular in China as in the West. Most Chinese patients do not have good knowledge about medicines they need, and often just rely on and listen to their doctors' suggestions.
- d. Chinese government is implementing price reduction every year for a number of drugs to ensure that most of ordinary Chinese can afford basic medications. However, at present the price reduction only affects those low end drugs. Almost all high-end drugs, in particular those imported or manufactured by the Western pharma companies in China, have not been affected yet.
- e. Traditional Chinese medicines at present still occupy a quite big portion of the entire Chinese pharmaceutical market. However, as mentioned earlier, most of the TCMs are considered only for preventive treatment.

### **How to overcome these hurdles**

- a. Those pharma/biotech companies wishing to enter the Chinese pharmaceutical market with their products must re-conduct clinical trials in China, at least a phase III trial. To this end, they need to get their clinical trial plans (written in Chinese) approved by the Chinese authority (SFDA) and then set up trial center(s) in designated Chinese hospital(s). Generally, they need the participation of local CROs to help. On the other hand, conducting clinical trial in Chinese hospitals actually benefits the Western pharma companies as the physicians participating in trial will be influenced

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by the positive results of the trial drugs and therefore would encourage their patients to take them.

- b. After the clinical trial(s), Western companies need to submit NDA to the SFDA for marketing approval. Again, it is better to have a local CRO who is familiar with government regulations to participate in the process. Also all documents for review must be written in Chinese.
- c. It is better for Western pharma/biotech companies to conduct the manufacturing of all materials of the approved drugs locally so that the drug price is acceptable to most of Chinese patients. If this is not possible, then the Western company must select high-end drug products that only target wealthy Chinese patients, which, as mentioned earlier, still represents a sizeable market. On the other hand, some life-saving drugs such as novel anti-cancer drugs are commonly directly imported from the West. Even though their prices are much higher than those of many locally made drugs, they are still popularly demanded by all kinds of Chinese patients, rich or poor.
- d. Same as in the West, drug distribution in China at present time also takes enormous efforts. Not only do the hospital physicians have power to prescribe a preferred drug, but also the managers of pharmacy store in each Chinese hospital have power to sell or not to sell a drug for a company. So it is better for the Western pharma/biotech companies also to have help from local drug distributors in order to more effectively sell their products in China. However, there are successful examples of independently selling drugs in Chinese market by a Western pharma company. AstraZeneca is currently hiring more than 2,000 sales representatives in China to sell their own drugs throughout the entire country, even in very remote areas such as Xinjiang Province, the farthest west province in China. It successfully reached the sales revenue of close to \$450 million in China in 2007.<sup>27</sup>

### 4.6.2 Tapping low-cost labor in China

#### 1. Establishing a wholly owned facility (either manufacturing or R&D center)

##### Advantages:

- a. Can completely control the operation;
- b. Can still substantially reduce cost;