



## Pharmaceutical Enterprises' R&D Strategic Alliance

### —— the Road for Small and Medium Sized Pharmaceutical Enterprises' R&D in China

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#### Abstract

Based on analyzing the status of small and medium-sized pharmaceutical enterprises in China, the paper explores the problems of these enterprises; Then it provided several feasible development strategies which are building pharmaceutical enterprises' R&D strategic alliance, starting from the corporate strategic view and combining with the R&D characteristics of small and medium sized pharmaceutical companies; Finally in order to ensure the Effectiveness of R & D alliance, we point out some points of what should be noted in the process.

**Keywords:** Small and medium-sized pharmaceutical enterprises, R&D, Strategic Alliance

Constant new drugs are the main source backing up the core competitiveness of pharmaceutical companies and maintaining competitive position in the market. The cycle of global pharmaceutical R&D is longer and the cost is much higher. The pharmaceutical industry's character "high investment, high-risk, high-profit" is embodied in pharmaceutical research and development links. In 2003, FDA only approved 35 new drugs. At the same time, Pfizer and GSK, two of the world's largest pharmaceutical companies, developed 3 new drugs since 2000. Ten years ago, the cost of developing a new drug was an average of 2000 million in Europe and in the United States, but now it has risen to more than 1 billion U.S. dollars (Xu,2005,P.61-64).

New Drug R&D is a system engineering, so it is impossible for the small and medium pharmaceutical companies' R&D departments to complete all the work independently. But they can combine with other small and medium pharmaceutical companies' R&D departments to share the R&D costs, R&D risks and R&D interests. For small and medium sized pharmaceutical enterprises in China, the pharmaceutical enterprises' R&D Strategic Alliance is a effective way to shorten R&D time, share the costs and reduce the risk.

#### 1. The R&D Status of small and medium sized pharmaceutical enterprises in China

##### 1.1 The definition of small and medium sized pharmaceutical enterprises

According to "The notice with regard to the issuance of the interim standards for small and medium enterprises" (SMEs Guojing Mao (2003). No.143), the industrial small and medium enterprises must meet the following criteria: the number of employees is under 2,000, the sales under 300 million Yuan, or the total assets under 400 million Yuan. Among them, medium-sized enterprises must make sure that the number of workers is over 300, the sales over 30 million Yuan and total assets over 40 million Yuan. In this article, the small and medium sized pharmaceutical enterprises are referred to the medical companies which the sales under 1 billion Yuan.

The R&D of small and medium enterprises in China has the following features: small size, short of capital, low level of technology and less competitive in the market. New drug development requires a lot of manpower, material and financial resources. So for many existing small and medium sized pharmaceutical enterprises, new drug development rely mainly on "me-too" drugs and few companies are able to develop pharmaceutical products with independent intellectual property rights due to the power constraints such as its scale, capital and human resources.

##### 1.2 China's small and medium sized enterprises pharmaceutical R&D contrast with large pharmaceutical companies

###### 1.2.1 R&D personal

China Statistical Yearbook data on high-tech industry statistics shows: in 2007, there are 5748 enterprises in China's pharmaceutical manufacturing industry, of which there are 67 large-scale pharmaceutical enterprises and 5681 small and medium enterprises; in 2006, the number of employees in China's Pharmaceutical Industry was 1.3 million, of which there are 245.2 thousand employees in large enterprises, accounting for 18.82% of the total and 1.0576 million employees in small and medium enterprises, accounting for 81.18% of the total; in 2007, china has 30778 full-time

equivalent of R&D personnel. Among them there are 11770 persons in large enterprises, accounting for 38.24% of the total and an average R&D personal of an large enterprise is 176. And it has 19008 persons in small and medium enterprises, accounting for 61.76% of the total and an average R&D personal of a small and medium enterprise is only 3.3. Therefore, the R&D in small and medium sized pharmaceutical enterprises is far less than the large pharmaceutical companies. The lack of new drug R&D talented person greatly limits the R&D capability of small and medium sized pharmaceutical enterprises in China.

### 1.2.2 R&D investment

In 2005, the percentage of the entire pharmaceutical industry R&D investment in sales revenue is only 1.02%. Apart from Jiangsu Hengrui Medicine Co., Ltd, whose R&D investment is 6.94%, the proportion of R&D investment in others is still at a very low level (Liu, 2007, P.36-38). According to the China Statistical Yearbook data on high-tech industry statistics, in 2007, the R&D investment of pharmaceutical industry is 6.6 billion Yuan, among which Large pharmaceutical companies spend 2.6 billion Yuan, accounting for 39.6% of the total, and the average is 38.9 million Yuan in every large enterprise; While that is 4.0 billion Yuan in small and medium enterprises, accounting for 60.39% of the total and the average is only 700.4 thousand Yuan in an small and medium enterprise. Because of limited investment in innovation, the research capacity of new drugs is low and Chinese enterprises rely too much on "me-too" drugs, less on innovative drugs. Domestic small and medium sized pharmaceutical companies are still focused on the more mature and relatively low-tech production. Which result in the varieties of similar productions, excessive capacity, Serious duplication, the lack of variety and technological innovation and homogenization of market competition. At this state, the enterprises can not enter the track of healthy development, which constraining the healthy development of China's pharmaceutical enterprises.

### 1.2.3 R&D System

The large pharmaceutical companies gradually set up a sound system for new drug research and development, found its own engineering and technology research and development centers as well as drug non-clinical safety evaluation laboratories. They can concentrate on their own advantage of core technology and core industries; meanwhile sustain the country's leading technology in the medical high-tech technology research. Many small and medium enterprises adopt a top-down "classroom model" in R&D. The topics and direction made by higher leadership is arranged down to R&D personnel. Then, there are two ways for researchers to choose: one is choosing and playing independently along the major directions and topics; the other is in full compliance with company CEOs, which is a record R&D system (Hong, 2004). This system impedes the development of new drug R&D in small and medium pharmaceutical companies.

According to China's current conditions, it is hard for small and medium pharmaceutical companies to do new drug R&D independently. Therefore, to establish R&D strategic alliances is the only way for small and medium sized pharmaceutical enterprises.

## 2. Small and medium sized pharmaceutical enterprises' R&D strategic alliance

### 2.1 The definition of strategic alliance

The strategic alliance refers to a loose network formed by two or more companies for a certain purpose or to achieve strategic objectives, through a certain form composed of complementary advantages, risk sharing, two-way or multi flow of elements. Strategic alliances are spontaneous, non-coercive and the Union parties maintain the independence of the existing business operations. It also has characteristics of fuzzy boundaries, operational efficiency, and flexibility (Porter, M.E., 1997, P.56).

### 2.2 The needs of small and medium sized pharmaceutical enterprises to implement the Strategic Alliance

#### 2.2.1 To solve short of capital and high risk for small and medium pharmaceutical companies

Implementing strategic alliances can make small and medium pharmaceutical companies achieve the goal which is resource sharing, resource complementing, reducing repetitive waste of resources, and focusing the capital, talent advantages on core project. With the use of other companies R&D results, they can compensate for the lack of corporate R&D resources to avoid putting in a lot of new drug R&D funds, thereby saving the cost of scientific research. At the same time, this R&D system which is implemented the Strategic Alliance, Refrain a number of enterprises from being engaged in a lot of research and development, and thus save the corresponding R & D process management costs. In addition, the R & D alliances between enterprises greatly reduce risk and increase the chances of success. And the enormous economic benefits that successful new products bring are immeasurable.

#### 2.2.2 To solve low technological level for small and medium pharmaceutical companies

Small and medium enterprises can learn from other enterprise technical know-how or some capacity through strategic alliances. The growth and development of enterprise is inseparable from their own quality improvement, new knowledge and new skills to learn. Learning form Coalition partner enterprise will also face being imitated, so

enterprises often want to learn faster than competitors, so that in the league will have a "learning race" phenomenon. Pharmaceutical enterprises' R&D Strategic Alliance not only promote the interaction and learning between enterprises, universities and research institutions, but also internalize external information and knowledge, activate the enterprise's internal resources and improve the competitiveness of knowledge-building and organization, which will involve more technology, human resources, capital and project inputs.

### 2.2.3 To solve the small-scale problem for small and medium pharmaceutical companies

Being implementing strategic alliances, small and medium pharmaceutical enterprises can combine together as a whole, which will deepen the division of labor and strengthen technological progress. So capital, technology, manpower, material resources, information and other resources among the different enterprises can be effectively flexibly mixed, which is to minimize product development costs. Large laboratory can buy more specialized equipment, so that experimental activities will be more effective. The problem which can not be solved before by the use of a particular field of subject knowledge alone will be solved by different experts in the field of technical cooperation. Thereby, economies of scale have come into being in research and development.

## 3. The choice of small and medium sized pharmaceutical enterprises' R&D strategic alliance

### 3.1 The patterns of small and medium sized pharmaceutical enterprises' R&D strategic alliance

At present, China's pharmaceutical enterprises R & D strategic alliances have the following two modes (Zhang,2009,P.95-97): One is an equity strategic alliance. Many producing, learning and researching centers build a community by joint venture which is a relatively strong knowledge of innovation and share results of joint research and development, and based on optimizing the human resources and inputs within the Union. It is founded by the members as shareholders, who have their own separate assets, personnel and management authority. Equity-type strategic alliances generally do not include the core business of members; the other is virtual non-equity based strategic alliances. Many industry, academia, research, suppliers, dealers, finance, securities, venture capital providers, and the ILO establish an extremely loose virtual network communities through agreements, contracts and negotiations, based on loose virtual network combining elements within the Union. When the core business within the union members is the same with the alliances and partners are unable to move its assets off the core business, or in order to achieve greater flexibility in contraction and expansion, virtual non-equity based strategic alliances will emerge when partners do not want to establish an independent joint venture companies.

The values of the two kinds of R&D strategic alliance model are embodied in sharing of complementary research results, reducing development costs, sharing risks and achieving sustained development of cost competitiveness. According to China's current status of pharmaceutical enterprises, small and medium pharmaceutical companies are more suitable for the virtual non-equity based strategic alliance.

### 3.2 The support system of small and medium sized pharmaceutical enterprises' R&D strategic alliance

Based on the characteristics of new drug development and combined with the actual situation, effective implementation of the R&D strategic alliance must depend on the support of a sound guarantee system (Wang,2005,P.111-113):

#### 3.2.1 Information exchange platform

An information exchange platform is established between research institutions of pharmaceutical companies or between medical institutions and pharmaceutical R&D enterprise. It can fully utilize the research results of the large number of scientific research institutions, with access to medical research results that they are lack of and the heterogeneous resources which are hard to replace, and finally realize resource sharing and complementing. By establishing good partnerships with research institutions, small and medium pharmaceutical companies expand variety of products effectively; filter out products that have bright market prospects, high technology content and reliable quality. This can effectively guarantee that small and medium sized pharmaceutical enterprises can develop in the fierce market competition.

#### 3.2.2 Businesses

Enterprises in the pharmaceutical industry include pharmaceutical manufacturers and pharmaceutical commercial enterprises. The smooth functioning of the platform needs a strategic alliance formed by pharmaceutical companies and a number of medical research institutions. This is a unilateral contract-based strategic alliance that is, a one-way economic behavior, that pharmaceutical companies purchase the research results from scientific research institutions; This alliance is formed through the combination of resources, using the complementary resource combinations and in order to achieve the aim that is complementary advantages and improving the competitive advantage between enterprises and research institutions.

#### 3.2.3 Auxiliary organizations

Here, the auxiliary organizations include suppliers, public service institutions, venture capital institutions and other

financial institutions. It is a unilateral contractual relationship established between auxiliary organizations and scientific institutions of the alliance, so it can adjust to accordingly with the external environment. In this relationship, the pharmaceutical business decision-making has greater flexibility: carrying out amendments according to the market dynamics, selecting the appropriate alliance members (research institutions), which can respond to changing market demands and maintain their market status. This flexibility and energy make the company continue to obtain scientific research of their own needs, accordingly reduce their capital investment in scientific research and achieve low-cost market expansion strategy.

### 3.3 *The issue should be paid attention to in Union*

Through strategic alliances, small and medium sized pharmaceutical enterprises' R&D not only can reduce the human, material and financial resources investment, but also the risk of new drug development, increasing the probability of a successful new drug development. However, there are still a lot of problems in the process of establishing strategic alliances (Wang,2007,P.167-168),(Lin,2004,P.16-18),(Parkhe A,1991,P.579-601):

#### (1) Conflict of interests among members of the alliance

The R&D strategic alliance reflects the cooperative and competitive strategic, including co-operation with competitors. This idea of competition through cooperation breaks the traditional strategy of confrontation. It is a cooperative game behavior, which is contributed to the overall friction reduction and makes full use of social resources. However, as time goes by, their interests may diverge because there are multiple partners. The alliance members must strengthen their own position.

#### (2) The inconsistencies of the Alliance's members

Strategic Alliance is the basic organization of enterprise strategies. Small and medium sized pharmaceutical enterprises' R&D strategic alliances have shifted the scope of competition from the enterprise to networks. The survival and development of strategic networks is closely related to the enterprise. Therefore, the small and medium sized pharmaceutical companies have to make itself as a node of the network, develop business strategies from the perspective of the strategic network and overcome the traditional strategy that the enterprise is as an autonomous entity of the state. However, it is dangerous to be over-relied on partners, suppliers or others outside the companies. Many small and flexible pharmaceutical companies are simply unable to organize coordination and cooperation in other pharmaceutical companies. When an innovation relies on a number of interdependent innovations, that is when the innovation is systemic, mutually independent companies often fail to coordinate and cooperate, nor can combine a range of innovative work closely together.

#### (3) The members of the Alliance pursue their own interests

The objectives of the strategic alliance should not only consider their own interests, but also consider the common interests of network. Strategic Alliance emphasizes the interactive relationship between businesses and other organizations, which decides that enterprises also highlight common interests, not just their own interests when they study the competitive advantage. For the common interests, enterprises is no longer meant to study whether it is advantageous for its own businesses in the strategic formulation, is no longer meant to study whether it is advantage but to the entire strategic alliance. However, with the incentive and the risk increasing, market-based co-operation of parties will become increasingly difficult. As time goes by, the result of innovation may be a surprise - perhaps not all participants can benefit from it, because too many interests involved and each act of partners starting from its own interests. As a result, previous friendly partners may be unwilling or simply unable to conclude alliances and cooperative projects which fall into this quagmire.

#### (4) The members of the Alliance pursue their own resource advantages

The competitive advantage of small and medium sized pharmaceutical enterprises' R&D strategic alliance derived from the resources, capabilities which all nodes in the strategic alliance network contributed and the integration of these resources by network. Each node focus on the comparative advantage activities in the value chain, effectively bring leverage into play and achieve competitive advantage. At the same time, all nodes contribute their core competencies to the network, resulting in a positive "network effects" by integration and management of the network value chain, and also access to a competitive network advantage. By using markets and external company, collaborative innovation has a variety of benefits: such as the rapid technological development, and technical improvements based on their resources. However, the open architecture as well as the retailer's independence will bring uninvited guests; some organization's network partner separate and choose at the fresh start; the same time, manufacturers who produce the same products will also emerge. Because other companies can buy the same raw materials, and sell by the same sales channel, this way, the companies can hardly control any critical resources, thus they are unable to establish their own competitive advantage. In order to maintain a leading technology status, companies must conduct a systematic technical collaboration tasks. However, when the initial joint-ventures are independent from each other, it is difficult to coordinate and cooperate.

(5) To collect information on new technologies and new product

Small and medium sized pharmaceutical enterprises' R&D strategic alliance will greatly affect Information Flow which plays a key role in innovation. As the company's managers continue to absorb new research results, the information about new technologies and new products which also conclude the early results of product testing and the initial customer feedback is also constantly expanding. Thus, if a research and development is carried out to achieve commercialization and profits, they must obtain large amounts of information from the rivals, customers and even researchers and carry out digestion and absorption. Such a vast and complex information-gathering and processing will not be easy, but if they can be handled in a systematically order, the task will be easier.

Small and medium sized pharmaceutical enterprises' R&D strategic alliance will suffer those problems, because the alliance can not overcome regulatory barriers between enterprise members. Alliance members have different interests, objectives and operating direction, when its benefit is greater than it created, the companies will be out of the alliance, the Union also dissolved. This alliance established by the company is flexible and dynamic then the relationship between members of the alliance is relatively loose, so the conflict of interest between members is less likely to happen. The responsibilities of members are very clear. There is no need to manage member firms strictly, thereby it will reduce the chance of regulatory barriers and the company can also effectively reduce the management costs.

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