

New factors pressuring China's API producers

Helped by competitive pricing and improved quality, China has in recent years emerged as a major global supplier of active pharmaceutical ingredients (APIs). But can the country's producers cope with increasing cost pressures? Dr Rob Bryant and James Shen look at some of the factors affecting the industry.

The generic pharmaceutical industry has developed over the past 30 years to supply lower-priced alternatives to branded pharmaceuticals, and establishing reliable sources of low-cost APIs has always been an important consideration for the sector.

The supply of APIs to US and European generics firms was dominated by Italy until the end of the last century, and more recently India has emerged as a major supplier. The main drivers of this shift have been comparative production costs and patent legislation, and many Indian exporters have also benefited from being a part of large groups with sizeable shares of the domestic finished dosage market. This has allowed manufacturers to develop APIs before starting exports.

We saw a similar situation in China, with the majority of producers deriving much of their income from domestic sales of finished formulations. As a result, the country developed a very strong position as a source of intermediates, both for India and other markets.

But, because of the attractive domestic opportunities, major Chinese firms did not start targeting the export of APIs until fairly recently. Changes to the Chinese regulatory regime and intensifying cost-containment measures in the 2005-06 period are some of the reasons for the shift, along with a move away from the export of intermediates over the past few years.

The Chinese industry has now become a major producer of APIs for the global industry (see table). Improving the quality and reliability of production has been key to this success. By July 2007, US FDA figures show that Chinese companies had lodged over 450 active drug master files with the US FDA, compared with 1,350 for India and 540 for Italy.

No of Chinese Firms Producing Top-selling APIs	
API	No of producers
atorvastatin	8
simvastatin	15
omeprazole	5
fluticasone	1
amlodipine	11
paracetamol	15
lansoprazole	9
ethinylestradiol	9
olanzapine	7
hydrochlorothiazide	1
salmeterol	1
pravastatin	7
amoxicillin	23
paroxetine	11

Source: SNAPI (Database-driven Sino API Intelligence).

Many of the major Indian companies have viewed this change with alarm and the smarter ones have invested in new Chinese manufacturing facilities, generally via joint ventures. Jiangsu and Zhejiang provinces have emerged as favourite locations, being within easy reach of Shanghai. While domestic companies still dominate the sector, the rapid rise of China's API industry has been supported by other foreign investors, with capital coming from Hong Kong, Taiwan and returning overseas Chinese.

Generally such approaches have been successful, although changes in China's financial, social and regulatory climate are now putting strains on emerging companies. While there have been green-field investments by some bigger players this year, costs in China are rising sharply due to a number of factors, including:

- increased global petroleum prices, which have pushed up energy and raw material costs;
- the Yuan/US dollar exchange rate, which has forced exporters to raise prices;
- changes to the government's export rebate scheme, which have contributed to export price increases in the past three months;
- increased pressure for environmental protection measures, such as investments in waste treatment facilities; and
- a three- to five-fold increase in salaries in big cities over the past five years.

While these have cut China's cost advantages, the country still has the lowest global cost base for API production and is likely to maintain its leading position for many years to come.

So what are US and European customers to make of the changes? What are the pros and cons of sourcing from India or China?

Both India and China have a highly competitive business culture based on cost cutting rather than product differentiation, which has been a headache for European producers since the early 1990s. India has improved greatly its attention to quality assurance and GMP issues and has also begun to develop more cost-efficient processes, allowing product differentiation. In these areas, the average Chinese company has some way to go to catch up.

For western firms, doing business in India can be more straightforward in some respects: English is widely used, the legal system is familiar and there is a reasonable understanding of western business practices. However, a poor infrastructure creates real cost problems. By contrast, China has seen spectacular advances in rail, road and air infrastructure, but business practices can be a concern, as can language. Intellectual property remains an issue in both countries.

Since 2005, changes to the patent regimes in both countries have also begun to limit the ability of domestic pharmaceutical companies to gain a marketing advantage over western firms. This has prompted some to search for alternative product development and API production locations, with new candidates such as Vietnam and Africa now emerging.

Nevertheless, the stage looks set for India and China to remain the major producers of both APIs and formulated products for the first half of this century. The winner will be the one that can best combine the three crucial requirements of western customers: reliability, timeliness and low cost.

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