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China Shining

07 December 2005 | News

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With a market size of over $20 billion, China will be poised to pose a threat to the Indian pharma industry in the years to come.

T he market in China in every segment is huge and growing, considering that it is the most populated country in the world and a rapidly growing economy. Doing business with China has been made more attractive by wide reaching series of reforms. But this is not easy. We have to scale the 'great wall' of regulatory and trade barriers and take on intense competition from local companies, and leading MNCs. In seeking markets for our products in China, chances are that we may end up procuring a few items, considering the hugely discounted prices of many products. That is China.

KV Balasubramaniam, Managing Director, Indian Immunologicals Ltd (IIL)	**BV Rama Subba** Rao, Manager - Exports, IIL

Sino-India Trade Ties

Bilateral relations between India and China have been steadily improving in the last two decades. In 1984, the two countries signed the Most Favored Nation agreement. The India China Joint Group on Economic Relations, Trade, Science and Technology (JEG) was established in 1988 during the visit of late Prime Minister Rajiv Gandhi to China. From then onwards, quite a few high profile exchanges and visits have taken place, resulting in constant strengthening of bilateral relations. The pharmaceutical industry in both countries has significantly has benefited fro this.

Market Overview

Health Sector

Before we understand the pharmaceutical market in China, we need to look at the user segment that it caters viz., health sector. Due to multiple factors such as higher living standards, enhanced health awareness and ageing, the health sector in China has grown at a steady pace of about 16 percent per annum over the decade.

China spends about 5.3 percent of its GDP on health related expenditure with a per capita expenditure of about $45 per head (Year: 2000). As per World Bank study of 1998, China should be spending about 10 percent of its GDP i.e., over $100 per head to take better care of the health of their citizens. In spite of several reforms and progress in this sector, infant and child mortality continues to be a matter of concern in China.

The public sector still dominates the health sector, and virtually there are no private hospitals, except for a few hospitals that cater to expatriates. For this reason, public sector pharmaceutical units that make 'me too' products at 'affordable prices' continue to flourish.

Pharmaceutical Sector

The market size of the Chinese pharmaceutical market is over $20 billion, making it the second largest in Asia, next to only Japan. Keeping pace with the growing economy, pharmaceutical market has witnessed a growth rate of over 14 percent steadily over the past 15 years. The market has so far been dominated by non-branded generics and the industry operating with basic technology and simple production methods.

With China's entry into WTO there are sweeping changes taking place. China's pharmaceutical industry is in a state of continuous transformation, with ongoing mergers, consolidations and new investments. In its overall drive for modernization, the Chinese government has implemented several major changes, including the reorganization of State Food and Drug Administration (SFDA), key amendments to drug regulation, bringing in WHO GMP standards along side enhanced intellectual property protection and changes in import drug licensing.

Intellectual Property protection

The Chinese government promulgated several laws in the year 2002, to improve Intellectual Property (IP) rights. As part of WTO accession, China extended all patent coverage to 20 years. SFDA is also putting in place many regulations for greater hormonization in regulatory and technical requirements, using ICH guidelines for reference.

Industry consolidation

Currently consolidation, alliance and acquisition are buzz words for growth and rationalization. The government continues to encourage regional mergers. Recent examples include the formation of Shijianzhuang Group in 1999, a combination of Weisheng Pharma, a Hong Kong listed joint venture and Hebei Pharma Factor, a leading antibiotic factory. The Shanghai New Asiatic Pioneer Group, which was formed in 2002, combines three major API factories; New Asiatic, Shanghai Pioneer and Shanghai No.3. There are many more examples of mega mergers.

GMP compliance is now compulsory for the renewal of manufacturing licenses. According to SFDA, the GMP regulations in force in China are largely based on WHO guidelines. It is costing each manufacturer a substantial sum of about $3.5 million to upgrade their facilities. As of now about 1800 facilities are certified and about 1000 facilities are uncertified. This is likely to result in mergers of financially weak enterprises resulting in industry consolidation.

Many companies in China want to work with West, not to secure any capital, which China sought in 1980s and 1990s, but for exposure to modern management and quality control practices. Ping Zhicun, president of NCPC Beta Company notes: "It is not technology we lack anymore, but the management techniques which have already been implemented and followed by Western pharmaceutical factories for years. For us to get up to speed will take years - a cooperation will enable us to lessen the gap quickly"

Custom manufacturing is another area factories are trying to develop, particularly for intermediates where there are fewer foreign regulatory requirements. There are exclusive facilities coming up in different provinces for contract manufacturing services.

Government support

The government is also playing its part to help pharmaceutical companies in their efforts to modernize. In July 2000, it announced that it would be encouraging non-pharma enterprises to invest in pharmaceuticals. This has resulted in quite a few large non-pharma companies pumping in fresh investments into the pharmaceutical sector. The government is also welcoming foreign investment in state-owned enterprises and has recently allowed them to invest in unlisted state-owned enterprises. The government is also funding liberally research institutions and encouraging their tie-ups with the industry. Pharmaceutical companies have also increased their R&D spend from an average of 1 percent of sales, just 5-6 years ago to about 5 percent now.

China is determined to become a major player in global pharma. When asked to identify the major Western misconceptions about China, Zhang Jianhi, CEO of Shandong Lukang, says, "Foreigners continue to underestimate the capabilities of China, both in terms of technology and quality but more over speed. They fail to recognize the significance and impact of past 20 years of continuous improvement and changes in China's pharma industry".

Long term threat should not obscure immediate opportunities for Indian companies for partnerships and supply arrangements particularly in API and Intermediates segment. We have to consolidate the early mover advantage that we have in pharma segment and accelerate further to stay ahead. From India, Aurobindo, Dr Reddy's, Orchid and Ranbaxy have established successful joint ventures. This is in the league of leading MNCs such as GSK, Bristol Mayor & Squib, Astra Zeneca, Boehringer Ingelheim, Johnson & Johnson and others, who have established their manufacturing presence long ago.

Vaccine Industry

China's human vaccine market size is about $800 million. So far the market was dominated by MNCs such as Aventis, Merck and GSK. Serum Institute had been exporting MMR and others to China. But the local industry is fast catching up with increased capacities and wider range. Well established state owned companies such as CNBC (China National Biotech Corporation) offer a wide range of vaccines including Japanese Encephalitis, Rotavirus, Meningitis (Group A+C), Typhoid vaccine and DTaP. They have established tie-ups with world leaders in various segments such as technology transfer, production, packing and marketing services. There are number of small vaccine producers such as Chengdu Institute, Lanzhou Institute, Shenzen Kangtai, National Vaccine and Serum Institute, Kunming Institute of Medical Biology and Beijing Institute of Biological Products. China has 7 vaccines in the EPI programme. Hepatitis B is the additional one product in the EPI list compared to India. China is in receipt of GAVI's support and this will continue till 2007.

Regulatory Framework

The State Food and Drug Administration (SFDA) was established in the year 1998 to oversee pharmaceutical product registration as well as importation. The pharmaceutical registration is extremely complex and also time consuming. This is due to the involvement of number of bodies at various levels of government and regions. Evaluation procedure is reportedly tougher for imported products in comparison to domestic ones.

It will take about 18â€“26 months for product registration, considering the level of rapport, you enjoy with the drug administration department. Conducting clinical trials on local population is necessary for biologicals and it is an expensive and time consuming affair.

Trade Barriers

China is reforming its tax system to minimize distinctions between domestic and foreign entities according to the WTO principles of national treatment. However, as a measure of protection for domestic industry, imports are restricted through a variety of means including non-tariff measures such as import licenses, import quotas and testing procedures.

Laws and regulations in China tend to be far more general than in most of the developed countries. This vagueness allows Chinese officials to apply them flexibly, which results in inconsistencies. Companies sometimes have difficulties determining precisely whether or not their activities contravene a particular regulation. Agencies at all levels of government have rule-making / interpreting authority, resulting in regulations that are frequently contradictory. Finally, while there seems to be no shortage of rules and regulations, there are few procedures in place to appeal regulatory decisions.

Animal Health Segment

As a result of heavy industrialization and export trade, urban incomes have risen significantly over the last two decades, but still around two third of China's 1.3 billion population lives in rural areas and dependent on agricultural output, where the incomes are less.

Live stock production is an important contributor (30 percent) to country's agricultural output. In response to the population growth and rising per capita demand, the livestock numbers and output of meat are steadily increasing.

Though the live stock numbers are massive and meat output huge, production is dominated by small farmers, often rearing a handful of animals. The 'back yard farmers' with five or less animals account for more than three fourths of the total pork production. Considering the size of meat production, China is still a minor player in export market for meat. Following China's accession to WTO trade barriers are dismantled and the country's export/import trade in meat product is likely improve significantly in the coming few years.

China accounts for about 8 percent of the world animal health market and is growing very fast. The turnover of its animal health market is about $1.02 billion with a growth rate of about 10 percent over the last decade.

The market is spread among local players, JVs and MNCs. While local players including joint ventures with MNCs have substantial capacities for AH products including biologicals, MNCs have strong presence with their high-end product portfolio and marketing muscle. MNCs such as Merial, Intervet, Fort Dodge, Pfizer, Bayer, Novartis and UBI have their presence with own manufacturing facilities / JVs / Acquisitions.

Market among the local players is highly fragmented with no one holding more than 3 percent market share, with the exception of CAHIC (China Animal Husbandry Industry Company Ltd) having about 20 percent market share in AH segment. CAHIC owns majority stake in 16 local companies and minority stake in 9 other local companies, including manufacturers of biological products. They have a huge, cross-country marketing and distribution network. Some of the MNCs also utilize their distribution network.

Animal Health Vaccine Industry

Consumption of veterinary vaccine is steadily increasing in excess of average market growth due to more intensive disease control programs. Regular administration of preventive vaccination is mandatory in respect of ten diseases, including swine fever and number of serious poultry diseases.

The local industry is building huge capacities for the production of FMD Vaccine, Poultry Vaccines and Swine Fever vaccines and a wide range of biologicals. For example the combined capacity of 4 leading FMD producers is in the range of about 2.0 billion doses of FMD. Qian Yuan Hao biological company produces about 14 billion doses of Avian Influenza vaccine to meet 30 percent of the domestic demand.

So far, their production was directed for domestic use and partly the vaccine market was catered to by the MNCs. As the industry consolidates, more and more local companies and JVs are likely to dominate the domestic segment and also offer competition in the international market.

A Giant in the Making

It can be observed that China is really a giant in the making in the pharmaceutical industry, in both the human health and animal health segments. They have a strong domestic market and very competitive factors of production. Until recently, they were inward looking and as a result not at par with western countries, or even India, on product quality or regulatory aspects. However, with China joining the World Trade Organization (WTO) and with growing aspirations to be a world player, they have begun the task of radically improving technology, manufacturing ability and regulatory standards. They will definitely pose a threat to India in the coming years, especially in the international generics market, where India has an early mover advantage. Likewise, their vaccine industry is improving its prowess and is bound to challenge India's current superior position.

To design our export strategy, China cannot be just looked at as a market which will import our products. It is too large to be served from an offshore location. More than that, it has to be looked at as a market where local presence is a must.

We must acknowledge their strengths, look to building complementarities in export trade and attempt to build strong and mutually beneficial relationships with good companies. It is in this manner that exports can be sustained in China in the long term.