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Biopharma consolidating

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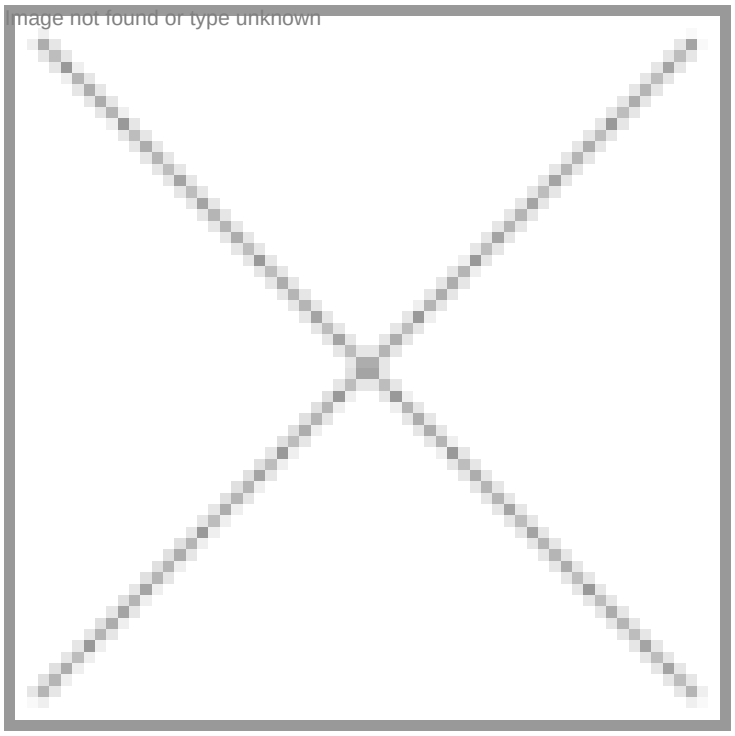

Biopharma consolidating

Both India and China have become World Trade Organisation (WTO)-compliant by meeting the numerous drug regulatory standards issued by the International Conference on Harmonization guidelines and the US Federal Drug Authority. The standards such as good clinical practices (GCP) have to be complied with-especially in the case of contract research organization (CRO) operations-to ensure long-term credibility. There are close to 70 FDA approved manufacturing facilities in India. BioSpectrum Advisory Services is working on a detailed report on this. In 2005-06 about 10-15 facilities are likely to get the FDA approvals. Clearly India is positioned to become a manufacturing hub.

India may become largest vaccine producer

There is a huge unmet need in emerging markets, which can been catered to only with a focused approach, driven by support from the leading vaccine manufacturers and increased role of private-public partnerships. New analysis from Frost & Sullivan Global Vaccines Markets, reveals that vaccines markets earned revenue of $9,925.5 million in 2005 and estimates to reach $20,019.1 million in 2012.

India has traditionally been a volume player, accounting for approximately a third of global sales, but a 10 percent share in value terms. "In order to achieve global leadership, Indian companies need to move towards a more value driven model comprising a mixed portfolio of products, targeting both developed and developing countries. This needs to be supplemented with aggressive marketing and cost effective R&D and manufacturing," said Utkarsh Palnitkar, health sciences industry

leader, Ernst& Young India.

The report also adds that unlike most of the biopharmaceutical markets, vaccines possess certain district facets, which enhance India's competitiveness. These include the presence of large institutional buyers, the generics-driven nature of the market and relatively lesser interest from large multinational players, who are increasing focusing on developing blockbuster drugs.

Renewed R&D focus

Indian and Chinese drug discovery outsourcing market is riding a crest with companies from outside Asia increasingly seeking to outsource drug discovery to these countries for greater cost savings. Other major factors driving this shift to Indian and Chinese companies are the better access to expertise, productivity gains, process improvements, and variable costs, avoidance of capital outlays and opportunities for companies to focus on specific niches.

The $7.3 billion Indian and Chinese drug outsourcing discovery market is evolving, with both gaining an edge in the global arena by producing a continual pipeline of drugs, which are approved faster than those produced in western countries. Both countries are uniquely positioned to manage and deal with the pressures to enhance clients' profitability, increase shareholder value and utilize the potential of new drug discovery technologies."Governments' initiatives to diversify the industry's drug discovery portfolio and develop infrastructure are expected to drive the growth rate of the drug discovery outsourcing market in India and China to reach $19.8 billion in 2011," said Dr Amarpreet Dhiman, EMEA Drug Discovery Technologies Team Leader , Frost & Sullivan.

50 branded biotech drugs

The Indian market too witnessing considerable growth in recombinant products. There were 50 branded biotech drugs in India and this figure could increase to 100 by 2010. In 2003-04, the Department of Biotechnology (DBT) estimated the domestic market for recombinant therapeutics at about Rs 405 crore. It represents about 3.2 percent of the total Indian pharmaceutical market and 1.6 percent of the world market for recombinant therapeutics. But according to a report on Recombinant DNA Therapeutic Products published by Technology Information, Forecasting & Assessment Council (TIFAC) in 2002, the market of approved recombinant therapeutics has been estimated to be about Rs 535.7 crore, which is approximately 3.2 percent of the total pharmaceutical market of Rs 165 billion in the country. However, with IPR in place in India opportunities exist for speeding up production facilities, based on licensing and other forms of cross-border relationships for all therapeutic products approved for marketing in India, namely Insulin, alpha interferon, hepatitis B surface antigen based vaccine, erythropoietin, streptokinase, and others.

The erythropoietin market in the country has been on the rise, growing at a rate of 20 percent. The EPO market was estimated at about Rs 75 crore. G-CSF market is about Rs 20-25 crore and growing at a rate of 25-30 percent. Similarly the FSH market is about Rs 20-25 crore with growth rate of 20 percent. Now the present market size for interferon is about Rs 55 crore. It is growing at rate of 30-40 percent. The insulin market in India is about Rs 251 crore and the human insulin market is growing at the rate of 40.5 percent. The present Hepatitis B vaccine market itself is about Rs 100 crore with huge growth potential. The Streptokinase market in the country is about Rs 80 crore growing at a rate of 25 percent. Considering the overall, recombinant biotech market in India at present is in the range of Rs 500â€“600 crore growing at a rate of 20 percent.

Of the 14 recombinant biotech products available in the country, local companies have set up the expertise to develop and manufacture seven recombinant biotech products namely Hepatitis B Vaccine, Streptokinase, human Insulin, G CSF, Erythropoietin, Human Growth Hormone and Interferon alpha 2b. The rest all are imported and marketed in India.

The indigenous production of these products by local companies has resulted in the drastic reduction of prices and at the same time led to increased consumption.