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BioManufacturing Consolidates

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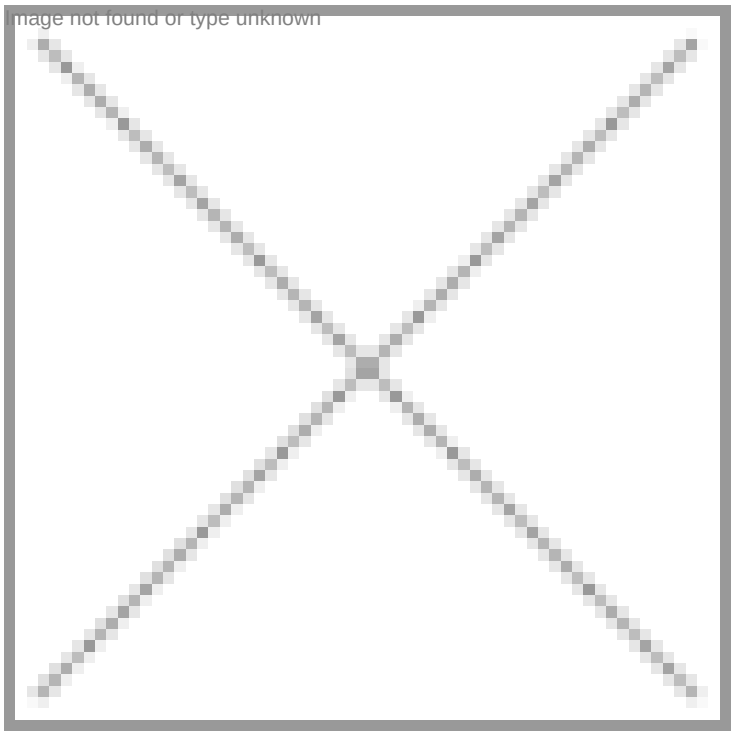

BioManufacturing Consolidates

While Indian companies are making significant investments to improve and expand their manufacturing facilities in order to enter regulated markets, global players are eyeing India to set up their manufacturing bases in the country.

Indian manufacturing matures complying with global standards. Today many companies in India and elsewhere are planning to make significant investments in R&D and manufacturing.

â€œBased on the knowledge about the facilities built by biotech companies manufacturing biologicals and the cost of vaccines, a very approximate estimate of the investments made would be of the order of Rs 1,000 crore,â€? said Varaprasad Reddy, managing director, Shantha Biotechnics, Hyderabad. Reddy does not consider the investments made in facilities for manufacturing fermentation based small molecule drugs such as statins, vitamins, anti-cancer agents and antibiotics. According to others in the industry, the Penicillin manufacturing facilities in the country alone have attracted close to Rs 750 crore of investment. And several companies have built manufacturing facilities complying with US FDA and EMEA norms.

It is not just the biopharma companies which are building quality facilities. Several other biotech manufacturers like those in the enzymes sector are building newer facilities. CL Rathi, managing director, Advanced Biochemicals Ltd, Mumbai which has been manufacturing and exporting cellulase enzyme for the last nine years, said, â€œWe now manufacture about 1000 MT (metric tons) cellulase enzyme per year. We are also now setting up a 100 percent Export Oriented Unit and are planning to invest over Rs 110 crore at Indore SEZ to manufacture cellulase, alkali protease, amylase, catalase, xylanase, acid and

neutral protease enzymes.â€? Rathi added, â€œOur investment in manufacturing has been about $2 million and we are further planning to spend over $25 million in next five years. We also plan to expand our manufacturing knowledge by setting up a plant in China.â€?

Similarly, Maps India Ltd, a biotechnology company producing enzymes and microorganisms, has signed a MoU with the government of Gujarat for investing Rs 10 crore for production of new enzymes and microorganisms during the current year. Celestial Labs is investing close to Rs 15 crore to set up an enzymes production unit in Hyderabad.

Besides multinationals also are now actively pursuing their plans to have manufacturing facilities in India. On February 22, 2005, Glaxo SmithKline (GSK), commenced work to set up a vaccine filling and packing unit for vaccines intended for India at Nasik. And it is expected to be fully operational by early 2006. S Kalyanasundaram, managing director, GlaxoSmith- Kline Pharmaceuticals Ltd, informed, â€œOur factory is capable of delivering vaccines to all children in the country. That is the capability we are creating at Nasik. GSK is able to manufacture and sell vaccines to the tune of 1.5 billion doses. If you look at the global population with newborn babies of 120 million, even if you assume 80 percent of our 1.5 billion doses goes to children, then every child will probably be consuming 8-10 doses of GSK vaccines. We are not only selling for children but also for adults.â€? GSK is investing approximately $20 million (Rs 88 crore) in setting up its vaccine filling plant.

Chiron Behring Vaccines Pvt Ltd, a wholly owned subsidiary of the Chiron Corp., has a manufacturing facility at Ankleshwar in Gujarat. The plant is based at the manufacturing complex of Aventis Pharma another major pharma company in India with which Chiron has a manufacturing agreement.

Sigma-Aldrich Corporation, the US-based $1.2-billion leading life sciences and high technology company and German pharmaceuticals and chemicals giant Altana AG are planning to set up facilities at SP Biotech Park, Hyderabad. UK-based Randox Laboratories would set up a diagnostics kit manufacturing unit in Bangalore.

India is now emerging as a favored destination for several reasons. Added Reddy, â€œDuring the last two decades, India has emerged as a preferred destination for cost competitive quality production of pharmaceutical API (active pharmaceutical ingredient) and formulations. Today, India enjoys the distinction of having the maximum number of US FDA approved facilities anywhere in the world outside of the US and has proven its claim to be a major manufacturing hub and supply center to the world. With the Indian IPR laws in place, the pharma manufacturing sector is expected to leap.â€?

â€œIt is not just a matter of cost arbitrage. Indian biopharmaceutical industry is moving up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards 1basic research driven, export oriented global presence, providing wide range of value added quality products and services,â€? added Kiran Mazumdar-Shaw, chairman and managing director, Biocon.

The focus of several Indian companies is to tap global markets and so they have focused on quality. For example, Biocon is now preparing itself to tap the US market for its Pravastatin and Simvastatin and working towards getting its plants FDA approved. Serum Institute has many of its products qualified by WHO. Shantha's Hepatitis B vaccine has been qualified by WHO. Panacea Biotec is in the process of becoming WHO pre qualified supplier of vaccines. Bharat Biotech got the approval from Korean Food and Drugs Administration for its human vaccines manufacturing facility located at Hyderabad. This helps Bharat Biotech to attain a level playing field and help reposition its entry into the global market. It has also signed an agreement with a South African company to set up a vaccine manufacturing plant in that country. It has signed an alliance with Wyeth International for manufacturing Hib vaccines.

Bharat Biotech, Biocon, Intas Pharmaceuticals, Shantha Biotechnics, and Wockhardt are some of the companies that are manufacturing rDNA products in India. Others like Glenmark Labs are serious on setting up manufacturing facilities for recombinant biotech products. Haffkine BioPharmaceuticals, Hindustan Antibiotics, Shreya Life Sciences, and US Vitamins have been into formulation business so as to produce for mass consumption.

Serum Institute has been investing about Rs 200 crore for expanding its manufacturing facilities at Pune. Biological E, which is looking at increasing its revenue from the biotech area by about 65 percent in the next few years, plans to consolidate its position in vaccine space by increasing the capacity and also by setting up a modern vaccine facility at SP Biotech Park at Hyderabad. It is investing about 36 percent of its sales on infrastructure development. Last year it has invested Rs 35 crore. This year it plans to invest Rs 44 crore again on infrastructure developments. â€œOur capex in the new plant is Rs 95 crore,â€? informed S Swaminathan, vice president (finance), Biological E.

Indian Immunologicals Ltd (IIL), a major player in animal vaccines manufacturing, has been making investments in infrastructure development in the last few years. IIL has invested Rs 50 crore last year against Rs 11.74 crore in 2002-03. Venkateshwara Hatcheries, a leading poultry vaccine manufacturer is entering manufacturing human vaccines.

Venkateshwara Hatcheries is investing about Rs 180 crore in phases. During first two years it will be investing Rs 60 crore and remaining amount in the subsequent years.

It is not alone the private sector that has made investments in manufacturing and upgradation of infrastructure. A public sector undertaking set up by Department of Biotechnology - Bharat Immunologicals and Biologicals Corporation Ltd - had invested Rs 38.9 crore on infrastructure development to formulate 120 million doses of Oral Polio Vaccine.

India has the largest number of pharma plants approved by USFDA outside the US. Indian pharma companies have also got certification from the European and Australian drug authorities. USFDA is now looking at opening its office in India. Industry sources say that soon this could become a reality. Commenting on the approvals, Dr Dhananjay Patankar, head - biotechnology, Intas Pharmaceuticals, said, â€œIndian companies can meet the GMP standards. Intas has already received the approval from TGA, Australia and MHRA, UK for bulk drug production. We know the system. It won't be a problem when a company comes out with a new drug.â€?

Bipin Deshmane, general manager, Shreya Biotech observed, â€œBesides Shantha only few companies in India are into manufacturing recombinant products. Others procure, formulate and sell in bulk in the domestic market. At present many Indian pharmaceutical formulation plants have received USFDA approvals. Companies such as Lupin, Biocon, JK Pharma, and Ranbaxy got the USFDA approvals for manufacturing few of their fermentation products. And I feel no Indian recombinant DNA product manufacturing company has received USFDA approvals for its manufacturing plant. However, the leading biotech companies including Shreya Biotech are working on aiming to have USFDA approvals so that they can enter the regulated market.â€?

Is India an R&D hub and China a manufacturing hub? In a few spaces such as diagnostic kits its true. Indian players find it difficult to face competition from Chinese players in terms of price. China made diagnostic kits are entering the Indian market at lesser price forcing the Indian companies to rethink to enter the same space. Dr SD Ravetkar, senior director, Serum Institute of India Ltd, said, â€œIndia is ahead of China in bio manufacturing. Already Indian companies are exporting vaccines, few recombinant products to third world countries at an affordable price.â€?

Expressing his views on few biotech products available in India, Dr Ravet kar said, â€œAlthough there are only a handful of biotech products launched in India, we will see more products in the country in near future as many companies are working on developing indigenous products. It will slowly pick up in the coming years. India has to gear up to launch new biotech products at an affordable price. For this to happen the government has to have a practical single window clearance system. Besides it should also look at faster implementation of Dr RA Mashelkar Committee recommendations. Along with the government, it is the responsibility of the individual companies to catch up with the latest developments taking place in R&D and update their skills and look for newer products so as to leverage on more and larger market. I still feel that biotech is still not happening in India. The mindset of the people should be to focus on quality issues as quality is key factor in biotechnology.â€?

While Indian companies are building up the capacities to enter the regulated market, there are some basic issues, which are hindering the growth. If the regulatory framework becomes clear one can see more companies making investments in bio manufacturing facilities in India. Varaprasad Reddy noted that the present regulatory position â€œproduct to processâ€? does not allow choices to the developer to make alteration or change of manufacturing facilities. This stance of USFDA and EMEA is the main issue of contention to allow or not to allow generic biologicals. Hence he felt the government should make an amendment to this position that would open opportunities for contract manufacturers to participate on toll manufacturing contracts for original developer of molecules and for manufacturing and marketing a generic version of the same on the expiry of patents.

Yet, contract manufacturing is a lucrative. Alok Gupta, country head, biotech and life Sciences, Yes Bank Ltd remarked, â€œIn biotech space larger biological companies are outsourcing their manufacturing or production part to Indian companies. The tie up between Wyeth International and Bharat Biotech International Ltd for filling facilities of Hib vaccines is an example. Similarly we have Biocon, which has signed a letter of intent to export recombinant human insulin to Bristol Myers Squibb. Hence companies should look at joint ventures/ initiatives to work together to reap profits.â€?

â€œWhile there are clearly established 'bio-manufacturing' capabilities these are largely in the area of proteins. We do not as yet have monoclonal antibodies being manufactured in India. The capabilities built up have brought a dramatic fall in product prices. A need for product differentiation is critical. At this point in time there is no clearly established pathway for 'generic' biologics, as is the case for pharmaceutical products. Accordingly access to the regulated markets is therefore not available. Exports are restricted to Africa, South America and some parts of Asia. Contract manufacturing has already commenced and one sees examples thereof in tie-ups such as Wyeth and Bharat Biotech.â€? added Utkarsh Palnitkar, industry leader, health sciences, Ernst & Young.

On the other hand Dr Dhananjay Patankar said, â€œThe leading Indian companies in biotech space have realized that they have to enter international market eventually the regulated markets. Hence they are focusing on in house manufacturing facilities. It helps to produce quality products and also make profits by entering the huge global market. About 7-8 companies in India have in house manufacturing facilities for biologicals. As biologicals are specialized products they need regular technical and R&D support. It also supports the growth of research and development (R&D).â€?

Globally there is an acute shortage of bio manufacturing capacity. Indian biopharmaceuticals can provide the manufacturing services as it has good manufacturing infrastructure for production of biotech products that would meet the global standards in terms of quality. The government support to the companies interested in setting up manufacturing facilities, by offering incentive package as being offer for R&D activities will be very helpful echoes the industry. Mazumdar Shaw, believes, â€œThe focus will be on indigenous manufacturing of recombinant drugs. In the next few years, the growth will be on account of both indigenous manufacturing and filling contract. A lot of activities are taking place in this front and many more companies will shift to bio manufacturing in the next five years.â€?

Ch. Srinivas Rao with Narayan Kulkarni and Rolly Dureha