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## **Injectables make manufacturers chant the niche mantra**



Going niche is the new mantra spawned by India's injectables players to gain a toe-hold in the increasingly toughening injectables generic space in regulated markets.

The generic injectables market is really hotting up. Some of the soon-to-be-off-patent injectables really offer the most promising opportunities. It is true that the number of injectable products that attracted generic attention is relatively small. However, indications are that the coming years are going to be really a tough time for those fighting to grab a share in the injectable generics pie. Case in point: the near-dozen carboplatin clones in the U.S. just after it went off patent. The competition and subsequent value erosions may not be as fierce as that of oral solids, but still, a larger number of players will be in the field vying for the lucrative injectable business.

Given the context, generic guys see the probable way out is to focus on those segments that attract less competition. Put another way, go for those that are niche or specialized. "While competition in case of injectables is no doubt growing, the trick lies in identifying the niche high-margin products which present challenges in development, analytics and manufacturing," said Ravi Seth, chief executive officer, International Operations, at Strides Arcolab Limited.

With 14 ANDA approvals for steriles already in the U.S. market, this strategy seems to have proven right for this Bangalore-based firm. Strides believes it can continue to focus attention on a number of similar product categories that offer very profitable opportunities. The firm makes a range of steriles - from immunosuppressants to gastrointestinals to antibiotics - from its manufacturing facilities located in Bangalore, Warsaw, Singapore, Milan and Lagos.

### **Vying for Less-Competed**

Orchid Pharma, another mid-sized player from southern India, has a similar strategy, although its product range is not as vast. Targeting cephs and penems, Orchid wants to position itself in the antibiotics segment of the U.S. market by 2009-10. The company has already lined up several niche products in these areas for launch through its marketing partners Hospira and Apotex.

Products with less competition are a quicker means of gaining access to the injectables space. Also, they can ensure relatively steady margins, unlike most of the high-profile products that are prone to risk in returns as competition flares up. Smaller market size and complex processes usually keep the leading players away from specialized injectables. But Indian firms

with strong chemistry skills could not only crack even tougher molecules but also produce them cost-effectively, believes Orchid.

The injectable market is also less crowded, with fewer players. Companies have historically face a high barrier to entry, given high degree of sterility requirements and difficulties in forming capabilities, manufacturing and supply. However, the scenario is changing. "Now we are seeing larger competition coming up with prices eroding much faster than it used to be three to five years before," pointed out Amish Vyas, vice president - International Business, at Claris Life Sciences. Nevertheless, this parenterals player sees significant opportunities in the U.S. market, banking on its strengths in injectable delivery systems. According to Mr. Vyas, Claris is one of the very few companies across the world offering a larger assortment of delivery systems in the injectables space, from multichamber bags, non-PVC/PVC bags, emulsion products to relatively simpler delivery systems, like products in ampoules and vials.

Besides delivery systems, Claris has gained expertise in manufacturing a variety of steriles too. The Ahmedabad-based company now wants to include lyophilized, oncology and pre-filled syringes portfolios into its FDA-approved ampoules and vials facility.

### **Leveraging India's Edge**

Even as firms like Strides, Orchid, Claris look at speciality products as their mainstay, there are others who bet on leveraging the India edge for the mainstream, high value products. Fresenius Kabi Oncology (formerly Dabur Pharma) is an example.

Fresenius, which secured ANDA approval for mitoxandrone in May 2008, is a noted player in cytostatics. Oncology leads the injectables generics market, followed by anti-infectives and CNS drugs. More than \$14 billion was spent on injectables used in the treatment of cancer in U.S., according to an Epsicom report.

The acquisition of Dabur Pharma in April last year helped Fresenius Kabi to strengthen its IV drug business in oncology. "Through its [Dabur Pharma's] expertise of APIs we became one of the leading companies in this product segment having the manufacturing expertise along the entire pharmaceutical value chain in IV oncology generics. So we are well positioned for cost and quality leadership in this product segment," commented a Fresenius spokesman.

The German drugmaker hopes access to India's labor market with its great pool of well-trained engineers and scientists would aid its growth needs, as it foresees increased use of generics in the coming days, due to continued cost-saving pressure in the healthcare sector.

Sun Pharma, Wockhardt, Zydus Cadila, Jubilant Organosys are among the other India-based firms having interest in the generic injectables business.

**- By S. Harachand**