

Why big pharma is busy acquiring injectables firms?

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Big pharma companies are gearing up to combat the shortage of injectables in the US through acquiring companies with approved manufacturing facilities. Last month, Mylan bought Strides Arcolab's injectable drug unit for \$1.6billion, paying the highest ever for an Indian pharmaceutical company.

According to Bloomberg, India-based Claris Lifesciences may be next in line to be taken over by one a pharma giant. Pfizer and Teva Pharmaceutical Industries have shown interest in acquiring this Ahmedabad-based company, which has five manufacturing facilities in Ahmedabad and has approval to ship drugs to the US.

Manufacturing injectable drugs require sterile facilities to protect against unwanted contaminants and the US FDA has cracked down on manufacturers that fail to meet safety requirements. Mr Srinivasa Rao Aluri, managing director, Morgan Stanley, in a telephonic interview, said, "The interest in buying injectables unit is high because FDA shut down a number of sterile facilities in the US so now these companies do not have sterile facilities to combat the contaminants and this pressure is making them acquire injectables unit from other FDA approved companies." In 2012 alone, FDA had sent 22 warning letters to a number of companies.

Ms Mridula Anand, researcher, Center for Leadership, Innovation and Change, ISB, believes that "With few players catering to niche segments, the injectables market poses high entry barriers to pharma and biotech companies. While due to stringent guidelines there are few FDA approved injectable manufacturing units in the US, the demand for sterile injectable drugs are growing. It is but natural for global firms to look towards India which have 'ready-to-run' sterile injectable drug manufacturing facilities."

Another reason for the spur in the interest to buy injectables is that there has been drug shortage of it in the US. In 2011, there were 251 drug shortages reported in the US, out of which 183 involved sterile injectable medicines, as reported on the FDA website. The agency believes that a major reason for these shortages has been quality issues apart from other issues such as production delays, among others. FDA acknowledges the fact that with fewer firms making older sterile injectable drugs, there are a limited number of production lines that can make these drugs. This small number of manufacturers and limited production capacity for sterile injections result in drugs being vulnerable to shortage and thus prompting the big

pharma to bridge this shortage gap by acquiring the injectables unit.

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Claris in 2010 was barred from selling its products in the US after the FDA found that the company was producing contaminated drugs. Claris, however, resolved the issue in 2012 and addressed the complaints following which it was allowed to resume US sales. Recently the company also got FDA approval for its ninth drug.

Pharma companies are constantly evaluating options for new innovative products while maintaining stringent quality. Firms such as Claris, Cadila, Dr Reddy's and Sun Pharma have developed strong manufacturing capabilities for injectables. Ms Anand further says "Claris has built capabilities across most verticals with a global presence and extensive regulatory approval experience which could prove valuable."

BioSpectrum tried contacting Pfizer for comment on this issue but the company declined by saying that, "We do not comment on market speculation or rumors." Pfizer was one of the companies which wanted to acquire Strides' injectable unit that ultimately went to Mylan.

Since there are a number of important players, who hold a strong ground in the injectables space, pharma giants are turning towards India to resolve this issue. Mr Aluri says, "Whether India is becoming a hub for acquisitions in injectables space is too early to say. This is a niche area and a lot of drugs are going off-patent. So this is a good trend that is happening. Same thing could be observed for biologics and this is a welcome trend that we are seeing."

Given the growing number of Indian firm's interest in biosimilars and biobetters, injectable therapies are set to play a larger role due to the challenge of formulating oral drugs. Ms Anand concludes by saying, "These general trends indicate a preponderance of Indian pharma firms emerging as either independent entities or collaborative efforts."