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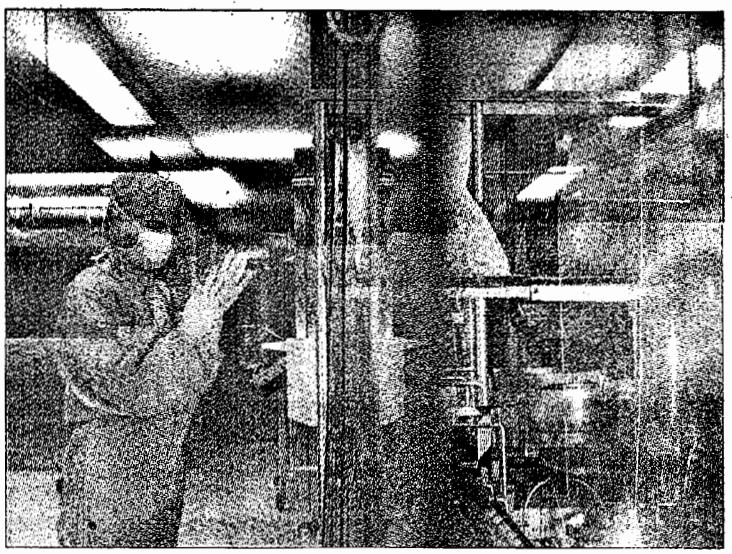
DRL plans ₹800-cr biologics spend before US, Europe foray

BV Mahalakshmi



The company had entered into an alliance with a division of Germany's Merck in June 2012 to strengthen its biosimilar segment

Hyderabad, June 25: Betting big on biosimilars, Dr Reddy's Laboratories has finalised plans to enter regulated markets such as the US and Europe. Currently, DRL has a portfolio of biosimilars, such as filgrastim, pegfilgrastim, rituximab and darbepoetin alfa, which have commercial presence in 15-odd emerging markets after a modest start in Russia in 1992. Ahead of its plan to enter regulated markets, the company intends to make investments of around ₹800 crore (an upper limit of $150 million) in the biologics segment in near future.

The company has already produced four biosimilars — rituximab called Reditux, filgrastim called Grafeel, darbepoetin alpha called Cresp and peg-filgrastim called Peg-Grafeel. Besides, it had entered into an alliance with Merck Serono, a division of Merck KGaA, Darmstadt, Germany in June 2012 to strengthen its biosimilar segment. The partnership is to co-develop and globally commercialise a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (Mabs).

Incidentally, the company had filed a US investigational new drug (IND) for the biosimilar rituximab in July 2013, and permission to proceed with the phase I trial under this IND was received during the year. It had also filed another US IND for the biosimilar pegylated filgrastim, which is peg GCSF, in December 2013 and the permission to proceed with the phase I trial in normal healthy volunteers under this IND was received in January 2014.

"In the biologics segment, two INDs have been filed during FY14, which have been accepted by the USFDA where more development will start. We are at the design phase. We have actually four currently and there are more in the pipeline in terms of development," sources said. For FY14, the company reported ₹113 crore from this segment in the domestic market.

The biosimilars portfolio has shown healthy growth over the recent past. Dr Reddy's is also actively marketing some of these products in select geographies of Latin America. In the next few years, a large number of biopharmaceutical drugs will be going off-patent in the US and Europe, and will so create significant revenue potential for companies in the biosimilars space. However, entries into such regulated markets necessitate clinical trials to prove efficacy of the biosimilar candidates. To address this, the company had entered into an alliance with Merck Serono, a division of Merck KGaA, Darmstadt, Germany.

Company