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Drug companies step up global investments to tap biosimilars

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Indian pharmaceutical companies are stepping up their investments to tap growing opportunities in biosimilars in Europe and emerging markets.

Cipla is investing ₹600 crore to set up a manufacturing plant for biosimilars in South Africa and Ahmedabad-based Intas is spending \$30 million (about ₹200 crore) for research into and trials of biosimilars.

The interest of Indian drug companies in this segment is evident as drugs worth \$90 billion will go off patent in Europe and the US in the next 10 years.

Biosimilars, which are copies of innovative drugs, are also expected to receive a boost as governments in developed markets try to reduce their healthcare budgets. On the flipside, however, growing competition is leading to price erosion and margin pressure for drug companies.

Biosimilars are made from living cells

and are far more complex and expensive to manufacture than generic drugs, which are chemical compounds.

"Our current turnover from biosimilars is about \$50 million (about ₹330 crore). Till date we have invested \$200 million (about ₹1,330 crore) and we will make an additional investment of \$30 million for manufacturing, research and trials. We are launching two biosimilar products in India each year," said Binish Chudghar, vice-chairperson of Intas Pharmaceuticals.

Intas launched biosimilar filgrastim, used in treatment of cancer, in Europe last February, a first for any Indian drug company. "We launched our first biosimilar in Europe last year and have filed for two product approvals in the US. We had an US FDA inspection in relation to the filings. We are carrying out the required trials and working hard to ensure compliance," Chudghar added.

Biocon has partnered US drug major

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Cipla, Intas Pharma, Biocon, Dr Reddy's Laboratories and other companies are investing in biosimilar development.

- Europe and emerging markets are focus areas for Indian drug companies
- Biological drugs worth \$ 90 billion to go off patent in the next 5-10 years. Domestic market for biosimilars could reach \$ 40 billion by 2030, according to a Assocham-Sathguru study
- Competition leading to price erosion of biologic drugs and impacting margins

Mylan for co-development of six biosimilars for cancer and auto-immune disorders. "We are on track for four regulatory filings of our biosimilars in developed markets in 2016-17, and have already made two of these. We are confident of being



among the first wave of biosimilars players to enter the EU," Biocon said in an e-mail response. Biocon had in July launched its anti-diabetes insulin glargine, its first such product in Japan.

"We have invested \$200 million in setting up an integrated insulin manufacturing facility in Malaysia. We are also investing in expanding our biologics manufacturing capacities in Bengaluru. The biologics business will contribute 20 per cent of our aspirational revenue aim of \$1 billion by 2018-19," Biocon said.

Dr Reddy's Laboratories (DRL), which launched its first biosimilar filgrastim in India in 2001, currently markets four such drugs in India and other emerging markets. It earned \$94 million from biosimilar sales in the three years till 2015. Like Biocon, DRL, too, has taken the partnership route for developing biosimilars in developed markets and has tied up with German drug maker Merck Serono for the purpose.

Sources said DRL was planning a \$300 crore investment over the next three years. The investment will largely be in the oncology space and plans include setting up a pre-fabricated facility for

biosimilars.

DRL refused comment on a specific query related to the investment involved.

While companies like Dr Reddy's Laboratories are looking at biosimilars, the country's biggest drug company Sun Pharmaceuticals is cautious because of ambiguity on several grounds such as approval criteria used by the FDA and whether the biosimilar can be a direct substitute to the biologic drug sold by the innovator. A company executive said, "Biologics is an expensive affair. One needs a separate set of sales persons for this segment. This means costs will go up dramatically. Thus, it is best we remain cautious."

"We see opportunities for Indian drug companies in biosimilars in local and emerging markets. We expect them to partner other companies for Europe and the US because research, manufacturing and marketing challenges are of a different magnitude," said Sujay Shetty, partner at PwC.