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# No biosimilars rollout for the next five years

## Regulatory hurdles, huge fund requirements hold up plans

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EVEN as Indian drugmakers are looking at biosimilars as the next big thing, it may take a few years before it kicks off as a mainstream revenue segment, given challenges like huge investments and regulatory hurdles in developed economies.

Existing players are, however, hopeful that things will look better in five years.

Biosimilars are bioequivalent versions of drugs and are made out of extracts from living organisms. These drugs are touted to have much better capabilities of disease management, including conditions that remain partially unaddressed by conventional medicines.

"Biosimilars is the answer to affordability as well as access. While developing economies are embracing it aggressively, the lobbying by Big Pharma is holding back regulators from advanced economies to easily give clearances, and so they set high bars of entry," said Kiran Mazumdar Shaw, chairman and managing director of Biocon.

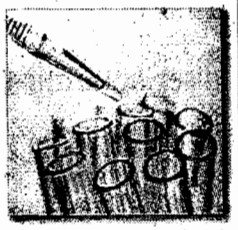
It is estimated that in the developing economies the market potential could be $5 billion in the next few years. "In the cost of developing one biosimilar drug, there can be 25-30 generics produced. Because only a few companies have the financial muscle and the risk appetite, developing biosimilars is not being taken up on a large scale. Things will definitely look different in five years because of abbreviated pathways," she said.

"No doubt it will take time for biologics to emerge in a big way because of the time, costs and patents involved," said G V Prasad, CEO and co-chairman of Dr Reddy's. "Serious pharmacutical companies will however get into consid ering the large scope, eventually."

Companies are looking at having tie-ups with global drugmakers.

Turn to P6

**New avenue**



**$20 billion**
estimated size of biosimilars market in '15

**$5 billion**
market potential in developing economies

**12 biosimilars**
get go-ahead in Europe, 1 conditional nod in US

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# Making of biosimilar drugs is complicated

From PTI

This will enable them to ease large-scale clinical trials and gain easy access to markets, especially in the US.

Indian companies which are keen to develop biologics include Dr Reddy's, Lupin, Wockhardt, Intas, Shantha Biotech, Biocon, Zydus Cadila, Hetero Pharma and Reliance Life Sciences.

So far, while Europe has given a go-ahead for 12 biosimilars, US has given conditional approval for only one diabetes drug.

"As of now, biosimilars are done only by a handful companies and it may take at least five years before things shape up. Although there are tremendous opportunities, only a very few companies are keen on developing because it needs huge investments. In fact, biosimilars now is what pharma was 30 years ago," said Dr P V Appaji, director general, Pharma Exports Promotion Council.

The global market for biosimilars is expected to be around $20 billion in 2015. Of the total market, India and China would contribute 70 per cent of it, as manufacturing and R&D here are much lower than other countries.

"The number of companies doing biosimilars will never reach 15-30 as these are complex drugs and the efficacy of the drug has to be proved in the clinical, unlike in generics. It may be a lucrative business but the making of these drugs is complicated," said an official from Natco Pharma.

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**New drug**

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- Europe has given a go-ahead for 12 biosimilars, US has given approval for one drug
- India and China would contribute 70 per cent of the biosimilar drug market

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