

NEW RISK

■ Pharma companies struggle to make copies of complex biotech drugs

Indian pharma faces biosimilar threat

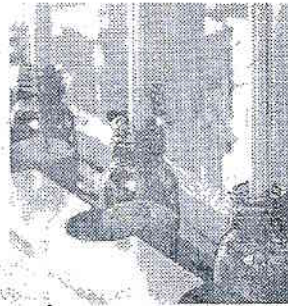
Mumbai, Oct 15: India, which has dominated the generic drugs industry for decades, is falling behind in the race to make copies of complex biotech drugs, which are expected to generate tens of billions of dollars in sales in the coming years.

While Indian firms have launched a few such products on the domestic market, where regulatory barriers are relatively low, they are being overtaken

by European, American and South Korean firms in the race to supply lucrative Western markets.

Just three Indian groups — Biocon Ltd, Dr Reddy's Laboratories Ltd and Intas Pharamceuticals Ltd — are working with partners on so-called biosimilars aimed at the United States and Europe.

Biotech drugs, which require genetic engineering, account for a growing share of new drugs and



the future sales of copycat products will also switch

to this category of pharmaceuticals from simple small-molecule pills like aspirin.

The global biosimilars market is predicted to have sales of \$25 billion by 2020, according to a news agency report.

"Biosimilars is a big opportunity," said Sujay Shetty, leader of the life sciences practice at PwC India.

"But unlike generics, it is not yet an opportunity

(for Indian companies) in the United States," he added. Copying chemical-based drugs has long been the bedrock of India's \$15 billion pharmaceuticals industry.

Biotech drugs, however, are more difficult to make and cannot be replicated exactly, which is why regulators have come up with the notion of versions that are similar enough to do the job.

That also means regula-

tors will be eagle-eyed on quality, posing a challenge to Indian companies, which have been distracted in recent years by manufacturing problems that have led to some drugs being barred from key overseas markets.

Many, including the country's biggest drugmaker Sun Pharmaceutical Industries Ltd, are still struggling to fix issues at their generic drug factories. — Reuters

Industry