

## Challenges and opportunities of biosimilars in India

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According to credit rating agency Fitch, the global biosimilar landscape is set to raise \$4-6 billion over the next few years from \$2 billion at present. Eight of the current 20 top-selling global pharmaceuticals are biologically synthesized drugs that will face patent expiry by 2020. Fitch believes that copies of human proteins such as erythropoietin-stimulating agents (ESA) and granulocyte colony stimulating factors (G-CSF) will most likely launch into the U.S. biosimilar drug market first. In 2013, however, the opportunity galore in biosimilar drugs is fraught with numerous challenges that broadly encompass technical, regulatory and commercial issues. Biosimilars, also known as biogenerics or follow-on biologics or biobetter are biotech drugs that have been shown to have comparable quality, efficacy and safety to an original biologic product. However the process to develop a biosimilar-essentially generic version of biopharmaceuticals-is more complex than that of developing a generic copy of a chemical-based compound. Over the past few years, China and India have been the up-and-coming destinations for international outsourcing of biopharmaceutical manufacturing. In recent times, industry research pointed to China and India as the industry's top potential destinations for offshoring over the next five years, which put them ahead of traditional biomanufacturing hubs in the US and Western Europe. India has the second largest USFDA generic companies next to US. Although none of the products can be considered as "true biosimilars", there are more than 40 biosimilar products in Indian market. 15 epoetin, 8 G-CSF and 4 insulin so-called "biosimilars" are on the market and more than 10 companies are competing in this area. The next big thing in the pharmaceutical industry will definitely be biosimilars and figures from the market analyses show that, emerging markets will have a big role in this area. The issues confronting the emerging opportunities of biosimilar in India will be discussed. Various resources used for deliberation are duly acknowledged.

### Biography

Pradip K. Mazumder is currently engaged as an Advisor in Krish Biotech & Krishi Rasayan group of Companies based in Kolkata, India. Mazumder obtained his Ph.D. from Indian Veterinary Research Institute in 1991. He obtained his post doctoral experiences from Human Molecular & Genetics, School of Medicine, University of Utah, Salt Lake City, USA. His research interest includes myocardial energetics with special reference to cardiomyopathy in Diabetes and obesity, molecular mechanism of type II Diabetes and obesity, NO biology. He published extensively in peer reviewed journals. He spearheaded much international collaboration in drug discovery & development in the field of metabolic and cardiovascular disorders. Mazumder is passionate about international collaborations, partnership and alliances in Pharmaceutical, Biotechnology and Agriculture sectors. Currently he assists medium and small enterprises with strategic planning, project financing, turnaround, structural and transformational changes. He enjoys global affairs, non profit organizations, music and sports.

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