

## Booster shot for biosimilar market: Pfizer-Biocon deal

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*The recent Pfizer-Biocon insulin products deal has created waves in the Indian biopharma industry. This deal opens a floodgate of opportunities for Indian biosimilar companies, in providing contract clinical/manufacturing services, and collaborating on other novel products*

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October 18, 2010 saw a major milestone in the global biopharmaceutical industry, with Biocon, Asia's premier biotechnology company, and Pfizer, world's leading biopharmaceutical company, signing a strategic global agreement, under which Pfizer will pay 890 crore (\$200 million) for exclusive rights to globally commercialize several of Biocon's insulin products - Recombinant Human Insulin, Glargine, Aspart and Lispro. Biocon is also eligible to receive from Pfizer, an additional payment of about 600 crore (\$150 million), towards further development of the drugs, and to meet regulatory milestones. Biocon would also receive payment linked to Pfizer's sales of the insulin

This deal enables Pfizer to get exclusive rights for commercialization of these products globally - with certain exceptions, including co-exclusive rights for all products with Biocon in Germany, India and Malaysia. Pfizer will also have co-exclusive rights with existing Biocon licensees, with respect to some products, primarily in a number of developing markets. Biocon will remain responsible for clinical development, manufacture and supply of these biosimilar insulin products, as well as for regulatory activities - to secure approval for these products in various geographies. Biocon's recombinant human insulin formulations are approved in 27 countries in developing markets, and commercialized in

23; while Glargine has been launched in India.

Commenting on this alliance, Kiran Mazumdar-Shaw, chairman & managing director of Biocon, says, "This, indeed, is a significant inflection point in our globalization path. Pfizer and Biocon together bring a winning combination of marketing, manufacturing and research excellence â€" that can build a formidable global footprint in diabetes care. Pfizer brings brand strength; besides a vast, unrivaled global marketing network - that will enable Biocon to realize its objective of seeing its insulin portfolio have a worldwide presence."

### Industry views

Reacting to the developments, Dr Rajesh Jain, joint managing director, Panacea Biotech, says, "It is indeed a positive step for the Indian biotechnology industry, as this deal signifies the acknowledgement of Indian biotech companies' research capabilities by multinational companies. In my opinion, it is just the beginning, that will spur the exponential growth of biotechnology space, both in India and globally. Such deals will certainly have a salutary effect on the industry, in general, and companies focusing on biosimilars, in particular. This deal will enable those companies to attract international investment and talent, more easily than before."

Commenting on the prospects of the deal, KV Balasubramaniam, managing director, Indian Immunologicals, says, "The deal is definitely a good booster shot for the biopharmaceutical industry in India, leading to more investment in this sector. Since this is a recognition of the growing competencies of the Indian biopharmaceutical industry, more specifically, its research and quality manufacturing capabilities. The companies that have a sound product pipeline and with recognized research capabilities, will benefit from similar deals. MNCs will cherry-pick products from established players in India, and look at sourcing cheaper from India."

"The domestic biosimilars market is not expected to see any significant changes due to this deal, given the dynamics of the insulin market in India. On the other side, globally, this deal can be very impactful on the biosimilar industry. So far, only generic pharmaceutical companies have participated in biosimilar markets, and have had limited sales and marketing expertise in selling branded products in the developed market. This was one of the factors responsible for low market penetration of biosimilar, so far. Pfizer's large sales force can help market these branded biosimilars more effectively, and can potentially garner meaningful market share," says KV Subramaniam, president & CEO, Reliance Life Sciences.

### Outcome of the deal

Sujay Shetty, associate director, Pharma Life Sciences Advisory (Corporate Finance), PricewaterhouseCoopers, India says, "The Pfizer-Biocon deal will have a huge positive impact on biopharma companies. At the same time, the deal has created confidence among multinational companies who are keen on working with Indian biotech companies that are building on manufacturing capabilities for future needs. Such deals will help Indian biotechnology companies to monetize assets they are building upon. This deal will open doors for other biosimilar companies as well."

KV Anantharaman, principal analyst (healthcare, research and analysis), Datamonitor, India, says, "The Pfizer-Biocon deal crystallizes Pfizer's entry into global biosimilar market, and fortifies the efforts of the Established Products Business Unit, that was created to counter the patent cliff that Pfizer was heading for. Pfizer's Established Products Business Unit, which is currently worth about 44,546 crore (\$10 billion), aims to stabilize its current base business, and transform it into a growing business segment, in order to capitalize on the about 2,000,000 crore (\$500 billion) opportunity, presented by the global established products market by 2011."

"The Pfizer-Biocon deal is a path-breaker in Indian history. It is a deal where an Indian company has developed a marketable product for which only clinical trials need to be done for the highly-regulated market. Also, the deal is amongst two biggest companies with no presence in the insulin segment, till date. It shows the prowess of Indian R&D, showcasing to the world, the capabilities of Indian companies, to develop not only generic medicines but also innovative technology-based products that can be taken to the world," says Dipta Chaudhury, program manager (Pharma & Biotech Practice), South Asia & Middle East, Frost & Sullivan.

This deal marks Pfizer's entry into the diabetes segment, which is one of the major growth drivers of the pharmaceutical industry worldwide - given that over 285 million people are afflicted by the disease globally. The recombinant human insulin market represents an estimated 62,000 crore (\$14 billion) opportunity; and will allow Pfizer to compete with well established competitors like Novo Nordisk, Eli Lilly and Sanofi-aventis.

**â€"Pfizer can help us to dislodge entrenched MNCs to gain market shareâ€"**

**-Dr Kiran Mazumdar-Shaw**, chairman & managing director, Biocon

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**Q How will the global commercialization agreement with Pfizer augment growth for the portfolio of Biocon?**

Pfizer brings huge brand strength to Biocon's insulin portfolio, as well as enormous credibility to our biologics capabilities. We believe that this quality endorsement from Pfizer will help us garner greater market share in global markets, where our products currently have a presence. Market share in India to increase, by eating into MNC brands.

**Q What is your expectation in terms of acquiring insulin market share both in India and globally?**

We expect to see increased market share in India and other markets where our insulin products have a presence.

**Q Why is the much-talked about oral insulin of Biocon excluded from this agreement?**

This is a novel program which is distinctly different from biosimilar insulins. Oral Insulin will be licensed as a separate asset.

**Q Since Biocon has a strong presence in India, what prompted you to agree for a co-exclusive rights deal with Pfizer?**

Despite being in the market since 2005, we have attained only 10-15 percent market share. We believe that Pfizer can help dislodge entrenched MNCs, to gain market share.

**Q How will this deal impact Indian biosimilar market and the global insulin market?**

Quality that is benchmarked with the highest international standards, will become increasingly vital to carve leadership in the biosimilar insulins segment.

Biosimilar insulins in the regulated markets of US and Europe will be solely dependent on physician prescriptions, and not substitutable like generic drugs. Pfizer will have the medical infrastructure to effect this, and make a commercial success of this portfolio.

**Pradeep Kumar** in Bangalore