

## Biotech Age

16 September 2005 | News

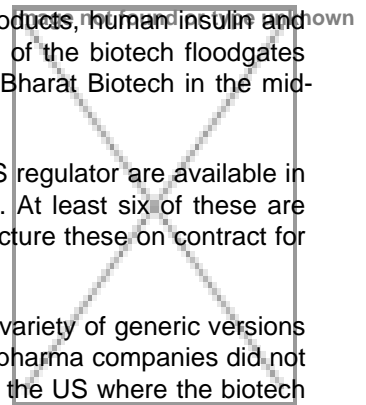


## Biotech Age

Slowly and steadily, the biotech era is making its presence felt in the country. The first biotech products, human insulin and hepatitis B reached the country from the developed markets in the early 1990s. But the opening of the biotech floodgates could be attributed to the domestic manufacturers like Shantha Biotechnics, Serum Institute and Bharat Biotech in the mid-1990s.

Today, the scene is vastly different. A fourth of the 50 recombinant DNA drugs approved by the US regulator are available in India. Indian regulatory agencies have approved the use of 14 biotech drugs in the past decade. At least six of these are manufactured by home-grown biotech companies. Then there are Indian companies which manufacture these on contract for global pharma firms.

It is indeed a remarkable change for a sector dominated by Indian pharma companies supplying a variety of generic versions of popular pharma products. Till the acceptance of the product patent regime early in 2005, Indian pharma companies did not have to look for biotech alternatives. They have now taken up the challenge to mirror the trends in the US where the biotech drugs are better placed to get regulatory approvals than the conventional pharma products.



The spirit of entrepreneurship is taking India into the brave new world of biotech with great gusto. Having realized the potential of this sector, the government too has pitched in by announcing a draft biotech policy, setting up the Mashelkar Task Force to formulate a modern and efficient regulatory regime for recombinant DNA pharma products.

Of course, from an end user's perspective, these distinctions between pharma and biotech products may not matter. And that is the way it should be. But in the long run, there could be a dramatic switch to biotech drugs if some of the unmet needs are addressed by the new class drugs. Especially, if the personalized medicine era dawns on the country in the forthcoming years.

This may already be happening in a small way. Many experts share the view that the pharma industry is at the end of its life cycle. Typically, every new industry has a 50-year life cycle and the pharma industry which started in the 1940s during the second world war is losing its steam. More biotech drugs were approved in the US last year than the traditional pharma drugs. The biotech is taking the pharma industry's place and the nearly 30-year biotech industry is entering its mid-life season. While pharma has become the mainstream, with no more need to canvass for the effectiveness of its products, biotech is bound to be the new industry. Public acceptance of biotech is increasing and biotech too is slowly becoming mainstream. The famous US cyclist Lance Armstrong, being accused of using a performance enhancing drug (biotech product EPO or erythropoietin) may have helped to turn the spotlight further on biotech products.

The opportunity is upon the Indian biotech industry. The industry's voice is now heard clearly by the policy makers. Almost all the hurdles facing the sector will be removed soon and the biotech age may certainly dawn upon us in India.

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