

New Regulatory Era

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The announcement of the implementation of most of the key recommendations of the Mashelkar Task Force on recombinant pharma products is good news. The exemption of LMOs from the purview of GEAC approval itself will take nearly 90 percent of the forthcoming biopharma products from the purview of the laborious regulatory approval process.

S&T Minister Kapil Sibal and DBT Secretary MK Bhan have used almost every public platform to reiterate that the government was working on other suggestions to set up a single-window regulatory structure. Their immense commitment to the biotech sector and the path-breaking changes introduced in the past 20 months gives the industry the hope that they will deliver on the promises at the earliest.

In the meanwhile, India also had another success with the biotech leaders at the BIO meeting in Chicago in early April. Sibal was in the forefront of selling the Indian story and he made big pitch to the global leaders to consider India as a destination to move the drug development process to make the new drugs affordable to more people around the world, leveraging the lower developmental costs.

The biotechnology industry celebrated its 30th anniversary. The modern biotech industry traces its origin to the founding of Genentech, now a \$6.2-billion giant, in April 1976. The BIO convention started in a small way in 1991 and has emerged as the world's most preferred biotech meeting with over 19,000 participants at the 14th edition in Chicago from 62 countries. The trade show has become really big almost all the major companies and most of the states in the US and European countries

using the platform to attract biotech entrepreneurs.

Asian countries have managed to attract attention in the last few with single pavilion which are getting bigger and bigger with each passing year under the country banner. Japan, China, Australia, Korea, Singapore, Taiwan and Malaysia have managed to get good attention using this route.

India has been doing this for the past few year. But unfortunately, Indian efforts were scattered under two banners-CII and ABLE- and two other major companies participating separately. The \$1 billion and growing industry is still small by global standards and the time has come for industry leaders to present a united front to the world at BIO. Industry leaders are unanimous that DBT should take up the leadership on this front too at least for the next edition of BIO scheduled for May 2007 in Boston and facilitate participation of India's most promising biotech companies under the country's banner. Collective resources of the country should be used intelligently and smartly, like our other Asian neighbors.

While India and China continues to attract the attention of global policy makers and industry leaders in the life sciences sector, the industry is looking at the big picture for the next decade. Clearly, two new segments are emerging as the next big things in biotechnology: Biofuels and industrial biotechnology. Recent breakthroughs in enzyme technology have dramatically increased the yield and reduced the production cost of ethanol from agricultural waste.

US President George Bush was quick to grasp the importance of this to lower America's dependence on imported petroleum products and shift to biofuels. Major policy changes have been made to boost the country's energy independence and now almost every influential American leader, including former President Bill Clinton, has become a champion of biofuels. Industrial biotechnology is the beneficiary of the advances in enzyme technologies and is in fact being referred to as the biotech industry's third wave. India has some headstart in these two emerging areas and we should build on these strengths and grab the emerging opportunities.