

News Details

National biotech policy urged to harness outsourcing trend

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NEW DELHI, Apr. 16: With companies from the US and Europe looking for outsourcing clinical trials, manufacturing and technology transfer, Indian industry has urged the government to formulate a national biotechnology policy.

"Though several states like Karnataka and Andhra Pradesh have formulated a biotechnology policy, a national biotech policy is still awaited," said Krishna M. Ella, chairman of the FICCI's Biotechnology Committee at a news briefing here on Friday.

Earlier this month, the government set up a task force on pharma biotechnology, which was one of the suggestions mooted by leading industry lobby Federation of Indian Chambers of Commerce and Industry (FICCI) to review existing rules and formulate new ones, FICCI secretary general Amit Mitra said.

The new rules are being sought to safeguard against manufacture of hazardous micro-organisms, genetically engineered organisms or cells.

In the memorandum submitted to the secretary in the ministry of environment and forests, right from seeking clear definition and distinction between biotechnology and pharma companies to gene technology and micro-organisms, FICCI has highlighted many of the dangers inherent in the present multiplicity of authorities.

"The current multiplicity of authorities at both national, regional and state levels are not only delaying approvals but leaving loopholes for a company to go to five different authorities with different products for approval," said Ella, chairman and managing director of Hyderabad based Bharat Biotech.

A leading biotech company, Bharat Biotech has received \$7 million funding from the US for developing new generation malarial vaccines.

With around seven months to go before the intellectual property rights (IPR) regime comes into force, FICCI is keen that India has in place safeguards to encourage foreign companies to form strategic alliances with Indian biotech companies for development of new molecules.

"While India has been practising conventional methods of biotechnology, the use of modern biotechnology is relatively new and therefore several vital issues such as IPR, biodiversity bill, etc., need immediate attention," said Ella.

Among the suggestions mooted by the FICCI committee is amendment of India's patent legislation to include "gene constructs" under the permitted categories to avoid hassles related to interpretation by the customs.

"India should also provide data exclusively to clinical trials and not permit use of the same data to introduce generic drugs in the same category," said Ella.

To boost research, the biotech committee has also urged certain conditions for employees of biotech companies to prevent any leakage of classified information.

Through harmonisation of different legislations, the committee has urged for a fast track mechanism, for clearance of biotechnology products for commercialisation and clinical trials, and single window clearance for biopharma and genetically modified products.

Citing Cuba's example, Ella said India too could use its large pool of talent to capitalise on the trend of outsourcing by European and US companies.

To help India emerge as a biotech hub, the FICCI committee has also mooted creation of a fund that would provide trained biotech graduates the seed funding to become entrepreneurs.