

Biotech sector requires special attention says FICCI

01 April 2014 | News | By Rahul Koul Koul

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FICCI's recommendations for the next government for year 2014-15 (as conveyed exclusively to the *BioSpectrum* by Shobha Mishra Ghosh, senior director, FICCI) :

1. As per FICCI, some of the key expectations from the government for Biotech include continuous flow of funds, increase in weight tax deduction from 200% to 250% and extending its applicability to activities like clinical trials, setting up venture capital funds, tax rebates, grants for advanced skills development programs, exemption from excise/custom duties on life saving medicines as well as on their raw materials and also on capital goods and consumables, CRO's and diagnostic kits. Additionally, the rate of Central Excise duty on bulk drugs which is 10% may be brought down at par with drug formulations which is 5%.
2. Further, with a view to encourage biotech exports; apart from the already approved Biotech Parks (BTP) schemes in states like Karnataka, Tamil Nadu, Andhra Pradesh, Uttar Pradesh and Maharashtra, it is recommended that the new government could look at increasing the number of BTP schemes for manufacturing and also cover the trading units under the purview of such schemes.
3. It is important that export incentives under the BTP schemes are revived for this sector to realize its full potential. Since, research and development in biotech, especially the Biopharma sector is highly capital intensive; export tax benefits will help the major industry players in de-risking and funding their original research, thus increasing manufacturing in the sector.
4. At present, 100 per cent FDI is permitted through the automatic route in Pharmaceuticals. As per the DIPP data, FDI in the

pharmaceutical sector jumped by 86.5 per cent to USD 1.08 billion during April-October period (2013-14) of the current fiscal amid concerns over continuous mergers and acquisitions of domestic drug makers by multinationals. Nonetheless, delays in approvals for clinical trials, regulatory issues regarding uniform code for sales and marketing of pharmaceuticals and compulsory licensing did have an adverse impact on the pharmaceutical industry. With respect to the Pharmaceutical sector, it is recommended for India to now move ahead towards break-through innovation in pharmaceuticals and new products with increased visibility should start contributing in Life-Sciences. Now daysvarious Pharma companies are incurring substantial expenses in creating innovative products/processes which can be patented. As an incentive for keeping such patents, technical know-how and other Intellectual Property Rights (IPR) in India a deduction/exemption should be provided by the government in respect of royalty and other income related to such IPR. This would help in improving trade balance and also keeps the emerging IPRs in India.

5. Since biopharmaceuticals involve formulations based on biological products, their guidelines regarding pricing should not be same as that of the chemical drugs. Therefore, it is suggested that the government (National Pharmaceutical Pricing Authority) should come out with sector-based pricing mechanism for different streams of drugs like Biosimilars or Biologics urgently so that the sector realizes its full potential.

6. As an Industry's voice, FICCI believes that there is a need for partnership between industry and government, especially for the biotechnology sector particularly in vaccines, biosimilars and regenerative medicine, and institutionalizing policies that enable faster market entry at lower costs, without compromising product quality, safety and efficacy.

7. Enhancing innovation and improving market access for biotech products are one of the many defining goals of healthcare reforms. FICCI is of the view that it is important for the coming government to provide support and work towards empowering the entire innovation ecosystem. One of the primary mandates of the new Indian Government could be to trigger, transform and tend biotech-startups to convert innovative research in public and private sector into viable and competitive products and enterprises.

For the past one year, FICCI has been actively organizing innovation Boot-camps and Sandboxes to identify the innovators in the country who can interact with Policy-makers, Investors and the Industry on one platform.

8. With objectives to foster a generation of ideas with commercialization potential, to up-scaleand validate proof of concept for innovation, stimulating enterprise formation and to encourage researchers to take up technology closer to the market through a start-up; the Indian government can certainly enable the Biotechnology sector to become "The Bio-Innovation" market across the globe.

FICCI feels that incorporating the aforementioned recommendations into its agenda, the Government 2014-19 will help the Indian biotechnology industry grow significantly in the coming financial years.