News

India poised to be major global biotech player

Rajashree Sharma

Thursday, February 17, 2011, 08:00 Hrs [IST]

India is emerging as a force to reckon with in the global pharmaceutical arena. The Indian pharmaceutical industry is globally ranked second-largest by volume and is likely to lead the manufacturing sector of India. As per BioSpectrum—ABLE Biotech Industry Survey r India's biotech industry clocked a 17 per cent growth with revenues of Rs14, 199 cr in the 2009-10 financial year over the previous fiscal. was the biggest contributor generating 60 per cent of the industry's growth at Rs.8, 829 crore, followed by bio-services at Rs.2, 639 crore a at Rs.1, 936 crore. Top 20 biotech companies contributed 52% of the total revenue and these companies grew at an average growth r 22%. The Indian Government's Department of Biotechnology also expects annual sales of the biotech sector to cross US$ 25 billion by 20

Biotechnology is an umbrella term that covers a wide spectrum of scientific applications used in many sectors. The national and ir biotechnology industry is now at the beginning of a technology curve whose upside potential appears limitless. The Indian government is biotechnology as the next driver of innovation and economic growth. Biotechnology has made phenomenal success in India in almost all primarily in healthcare.

Biological products include a wide range of products such as vaccines, blood and blood components, allergenic, gene therapy, t recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these sub may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or micro-organism be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, are at the forefront of research, and may be used to treat a variety of medical conditions for which no other treatments are available

"Biopharmaceuticals" are biological medicinal products that are developed by means of some biotechnology practices such as recomb controlled gene transfer/expression, and monoclonal antibody production. Biopharmaceuticals are emerging global healthcare products, panacea for many serious and life-threatening illnesses.

The Indian biopharmaceutical sector is today offering stiff competition to its global competitors and is poised to excel in this area. The market consists primarily of vaccines, therapeutic drugs, insulin, animal biologicals, statins and diagnostics. The vaccine market continues growth of the biopharma segment and growing in the range of 10-13 per cent in the next five years. The market clearly shifts to combinatic such as pentavalent vaccines and comprise a largest component. It's worth mentioning that the vaccine segment such as human as wel vaccines accounted for 50-60 per cent of the total bioPharma market.

India's 'similar biologics' (biosimilars) market is at a nascent stage but has considerable commercial potential. It is expected to reach a million by 2012 and about 50 Indian biosimilars have already reached the country's markets and some being sold in the unregulated mark Biosimilars are similar, but not identical, to already registered biological medicinal products in terms of quality, safety and efficacy. Unlik common "small molecule" drugs, biosimilars generally exhibit high molecular complexity, and may be quite sensitive to manufacturi changes. Verification of the similarity of biosimilars to innovator medicines remains a key challenge.

The inventive skill and efficiency of the private sector has to the success and resilience of the biotech sector. Stiff competition amo domestic manufacturers, and the need to balance between doing innovative R&D and delivering affordable quality products have turned top bio-pharma producer particularly in vaccine.

The collaborations and public-private partnerships in the biotech industry are on the rise. DBT and other organizations have pro-actively number of initiatives in creating trained human resource, institutional infrastructure has taken initiatives such as Small Business Innovatio Initiative (SBIRI) and the Bill & Melinda Gates Foundation are some of the examples of collaborations between government and industry. A some reports,DBT has also tied up with UK-based Wellcome Trust to enhance cutting-edge biomedical research in India. PPP will be the

affordable solutions to the pressing national needs of health care sector and at the same time it must be competitive enough to take advar lucrative international markets

Regulatory framework

The DCGI is responsible for approvals of preclinical and clinical trials, new drug applications, and the importation of drugs from abı biologics. In the case of biological products however, additional approvals are required. Once the proposal is made through Institutional Committee (IBSC), the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology (DBT) examines the data and recommends the application to the DCGI for human clinical trials on the basis of pre-clinical data. The Recombinant Dru Committee (RDAC) under the DCGI approves the protocol and recommends conducting of human clinical trials. For marketing license, a approval application is to be filed before the DCGI. Yet another committee, the Genetic Engineering Approval Committee (GEAC) under t of Environment and Forest (MoEF) examines information on containment facilities and data on clinical trials in respect of recombina products (LMOs) and accords environmental clearance.

To streamline the regulatory process, step - wise procedures (five protocols) are recommended. The mandate of the task force was to current framework and recommend a transparent and streamlined regulatory mechanism and process for the use of living Modified (LMOs) in the pharmaceutical industry during the various stages of R & D, testing, manufacture and import of LMOs as drugs.

Biotechnology Regulatory Authority of India Bill 2010 has been proposed to introduce single-window mechanism and received the Cabin seeks to create a new body to regulate research, manufacture, import and use of products of modern biotechnology

Biologics, biopharmaceuticals and recombinant therapeutics promise potentially cheaper alternatives but at the same time, it needs to be e the quality, safety and efficacy of such products are not compromised. In view of the above, the following “Guidelines for Preclinical Ev Similar Biologics” have been developed to provide guidance to applicants for generating data for approval of similar biologics and reg evaluating the submissions. Now comments on the guidelines are invited by DBT to incorporate important observations made by the sta and organize workshop on the guideline. Another guideline is expected from DCGI on clinical studies and both the guidelines will have a effect for approval of similar biologics.

In view of the above facts it is clear that India is the next big destination for international biotechnology companies. With the right kind of f collaborations between the government, domestic and foreign companies, the industry is set to grow tremendously in the coming years. I shifting its focus to the most promising industry of the future, biotechnology. The large pool of scientific talent and regulatory framewo come up for recombinant pharma, biologics and similar biologics will strengthen the approval procedures to pave way for quality biophar products and a vibrant biopharmaceutical sector. India thus presents a huge market opportunity and is well positioned to emerge as a player in the global biotech arena.

The author is Partner, Corporate Law Group,

Printer-Friendly Version Email This Article «« BACK

POST YOUR COMMENT

Comments

* **Name** :

* **Email** :

Website :

Submit **Reset**