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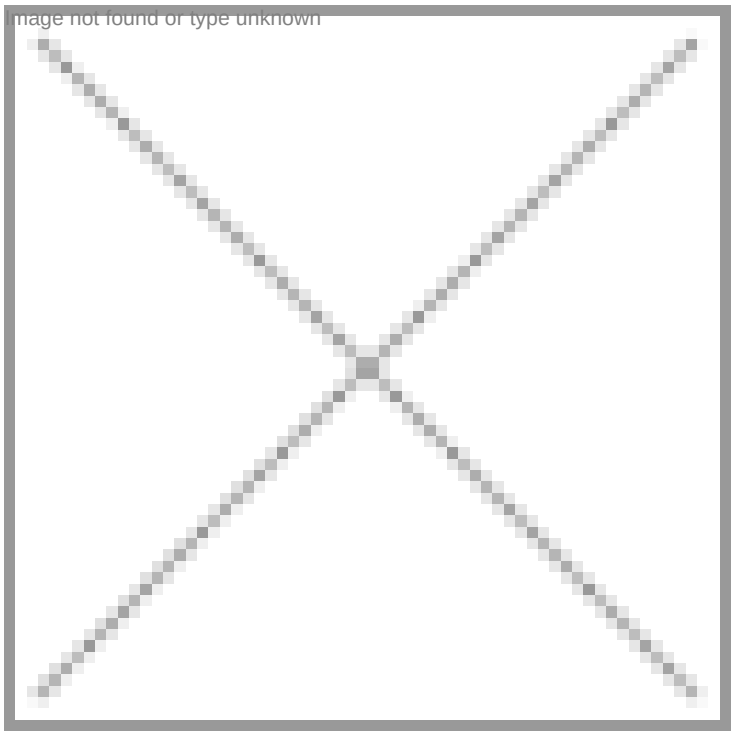

Indian firms eye Chinese BT products

Although there are no bilateral agreements between India and China in biotechnology research and development, Indian companies feel that importing biotech products for marketing will be a profitable proposition.

International collaborations in biotechnology are important for sharing and developing expertise, which would accelerate R&D growth. Towards this, India has signed bilateral agreements with many countries. It has about 14 ongoing and new bilateral programs and also other multilateral collaborative programs. But so far no joint initiatives have been made between India and China.

Contrary to this, companies including the pharma giants are looking at importing rDNA products and drugs from China for marketing in the country. Some of them have received approval from the Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment and Forests for conducting Phase III clinical trials. Pune-based Emcure Biotech has already received the GEAC nod for importing and marketing r-human Granulocyte colony stimulating factor rhG-CSF from Shanghai Sunway Biotech, China.

The GEAC has given approval for limited import of the products such as r-human granulocyte colony stimulating factor (rhg-CSF), Interlukin-2 (rIL-II), r human Erythropoitein, r-human interferon alphaâ€“2b, from China for conducting Phase-III clinical trials as recommended by the Department of Biotechnology (DBT) subject to statutory requirements under the EPA and Drugs and Cosmetic Act. A handful of companies are already signed, while a few others are still working out the possible deals. In terms of numbers of approvals from the GEAC, Chinese products are ahead since as many as five Indian companies are conducting Phase III trials to market these rDNA products in India.

Wockhardt Ltd has launched hepatitis A vaccine under the brand Biovac A, a Chinese product developed by Zhejiang Pukang in December 2005. According to reports, Wockhardt has no plans of getting the technology transferred to manufacture the vaccine in India. It has been permitted by the Centre to advertise the product and create awareness among medical professionals in the country.

Outsourcing activities

According to Utkarsh Palnitkar, director, life sciences, Ernst & Young India, China is actively involved in the field of vaccines, stem cells and gene therapy and can hence help India in these areas. Several of the biotechnology products manufactured in China are developed using recombinant technologies. Considering that the drug development costs in India are 1/8th vis-Ã -vis China's 1/5th of the global costs, it makes sense for Chinese companies to also outsource new drug discovery activities to India while both countries can proceed with pre-clinical studies and drug development simultaneously.

Securing rDNA products from China would benefit both partners since China is ahead in the technology while India has the marketing and distribution set up, which can facilitate export of Chinese biotechnology products to the US and more regulated markets such as the European Union. While the vaccines manufactured in China can be priced competitively for the Indian market, it offers the Chinese counterpart access to revenues from the Indian market.

Palnitkar added, "India is touted as the leading vaccine hub of the world. The Indian vaccine, biologicals and diagnostics opportunity is estimated at $821 million and can be attributable to the existing strengths in recombinant DNA technology. Several Indian firms are involved in developing recombinant vaccines indigenously. For instance, Indian Immunologicals was involved in developing a Hepatitis B vaccine. India's technology and marketing may prove complementary to the manufacturing prowess China has acquired in the area of rDNA vaccines, EPOs and interferons. These complementarities are likely to result in more collaborations between the two countries."

Sharing similar views, Nitin Deshmukh, honorary director, Association of Biotechnology Led Enterprises (ABLE), said," There would be two reasons for joint collaboration between India and China. One would be cost advantage. As far as development of biopharmaceuticals are concerned, Chinese products are on par with the Indian biotech products. The second one would be the regulatory approvals. It is would be easy for the companies to market if the product has already received the process approval elsewhere. Considering these two factors, Indian biotech companies are looking at establishing ties with Chinese companies. Companies would find it an attractive business model to work with companies from other countries."

Changing scenario

In the recent past the relations between two countries have improved a lot on many fronts. This has actually helped the industry to look at making investments in each other's territory. Companies in pharmaceuticals industry such as Ranbaxy, Dr Reddy's Labs, Orchid Chemicals & Pharmaceuticals and Aurobindo have made their presence felt in China. Similarly, Advanced Enzymes Technologies Ltd (formerly Advanced Biochemicals), an Indian enzyme manufacturer, has also opened a facility in China to serve its existing and new clients in Asia.

Considering the growing opportunities that exists between the two countries, the Federation of Indian Chambers of Commerce and Industry (FICCI) took a 13-member biotech delegation to Beijing, Shanghai, Tianjin and Nanchang in China in September 2005. During the visit, the delegation identified eight areas of interest such as collaborative R&D, speeding up of pre-clinical study, bioinformatics/chemi-informatics, free flow of biological materials, preferential incentives, exchange and technology transfer and human resource development where Chinese and Indian biotech companies could collaborate for mutual benefit.

Dr Krishna M Ella, chairman, FICCI National Biotechnology Committee, and CMD, Bharat Biotech International, who led the delegation to China, said, "There can be a free flow movement of biological materials, which include microorganisms and animals such as different strains of mice between two countries. If drugs are developed as a collaborated effort between India and China, these can be exported together to highly regulated markets such as the US, the UK and Australia. India can help to export Chinese biotech products to these markets and China can help India export drugs and vaccines to China by collaborating at a research level for speedy approval from the SFDA. There is scope for exchange and technology transfer of off-patented technologies to India, which have yet not been commercialized in China, and this may have a huge scope in the Indian market.

The governments of two big populous countries of the world should realize that opportunities exist at both the ends and encourage organizations by providing a proper investor-friendly environment for a win-win situation.

Narayan Kulkarni