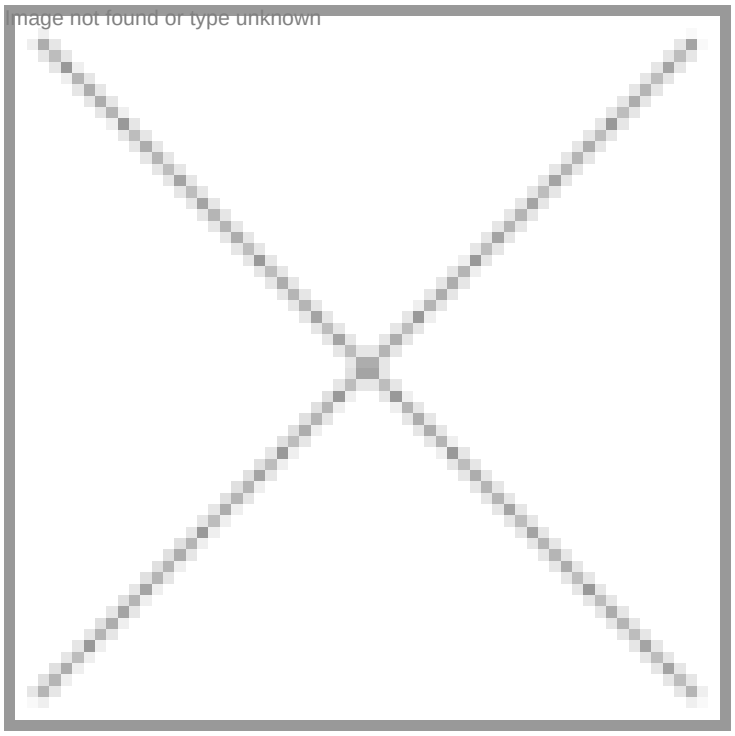
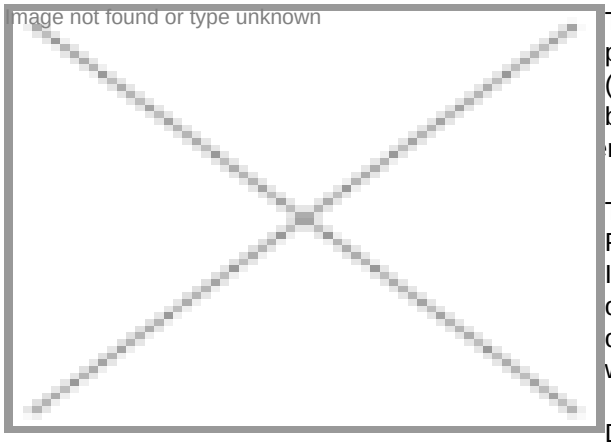
BioSpectrum
the business of Bio & Health Sciences

India biopharma will be $200 billion; industry by 2020

05 August 2010 | News





The biopharma market in India is growing at an annual growth rate of 15 percer By 2020, the market is projected to be worth over 938,688 cr ($200 bn), driven largely by a shift in usage from conventional drugs to biopharma products, the relatively high cost of biopharma products, the rapeutics.

This was stated by Ashok Kumar, secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India, while inaugurating the National Convention on Biopharma, organized by the Department of Pharmaceuticals (DoP) and Federation of Indian Chambers of Commerce and Industries (FICCI) in association with the Department of Biotechnology (DBT) and the Association of

Delhi on July 12, 2010. On the occasion, Ashok Kumar released the 'Vision 2020' document titled 'Leadership in Affordable Therapeutic Products: A BioPharma Strategy for India', prepared by PricewaterhouseCoopers and ABLE.

The report has exclusively quoted the BioSpectrum-ABLE Top 20 Biotech Survey, which was published in the June 2010 issue of BioSpectrum magazine. The report has used BioSpectrum data for providing the information on overall market size, rankings of the companies and other relevant figures.

The 'Vision 2020' document spells out the challenges before the biopharma industry and suggests key action areas for the medium-term and long-term.

The report states that if India wants to become the world leading provider of affordable biopharma products by 2020, itcannot simply count on biosimilars and vaccines; it should also become a source of innovation. More specifically, it should aim to have at least 10 original biologics on the local market and at least two on the global market by 2020. The report identifies five long-term (2020) initiatives and recommends that the government should make an additional â‚¹ 4,694 crore ($1 bn) fund available over the next 10 years to facilitate the growth.

Ashok Kumar said, â€œThe Government proposes to set up a â‚¹ 3,000 cr venture capital fund for giving a fillip to drug discovery and strengthening the pharma infrastructure in the country. The National Institute of Public Finance and Policy (NIPFP) is set to finalize the bid document and the expression of interest for setting up the fund will be issued this month.â€?

He further added that the government had issued an expression of interest for technical and financial bids for the selection of a global level consultant (GLC) for preparation of a detailed project report (DPR) for developing India as a drug discovery and pharma innovation hub by 2020.

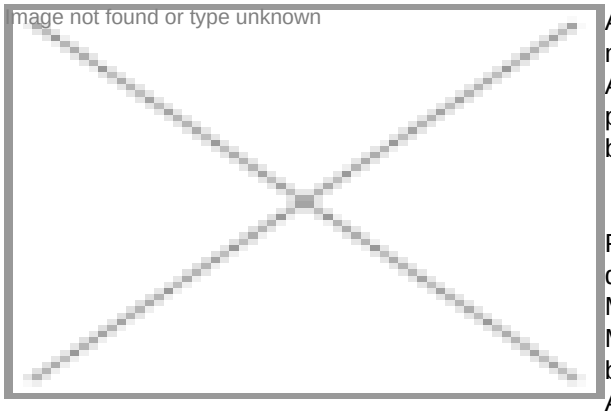
He said that the government is willing to look at the industry's demand for a single regulatory authority to do away with multiple regulatory bodies. At the same time, priority was being accorded to building the capacity of IP offices for approval and rejection of patents. He emphasized the need to create a talent pool of graduates in the biopharma sector, for which short-term courses that expose the graduates to the realities of the workplace, could be started by the National Institute of Pharmaceutical Education & Research (NIPER).

Dr S Natesh, additional secretary, Department of Biotechnology (DBT), highlighted that India needs to move from a phase of manufacturing to path of discovery and innovation.

Dr TS Rao, advisor of DBT highlighted the lack of availability of GCP-trained manpower in healthcare sector. He raised concern for the proper utilization of the already existing facilities set up by government and cautioned that careful need assessment is required for facilities to be effective.

Distinguished persons from the industry and academia participated in the event. The convention had different sessions on manufacturing, infrastructure and HRD, challenges and opportunities in biopharma industry and also a session on the regulations for biopharma industry.

Agricultural scientists call for revoking moratorium on Bt brinjal



A workshop for scientists titled, 'The impasse caused by the Bt brinjal moratorium', was organized by the Foundation for Biotechnology Awareness and Education (FBAE) on July 28, 2010, in New Delhi. As part of the workshop, there was an open discussion on the impact of Bt brinjal moratorium on R&D of genetically engineered crop in India and

Prominent agri experts including Dr Shanthu Shantharam, executive director, Association of Biotechnology Led Enterprises (ABLE); Dr TM Manjunath, consultant of agribiotechnology and IPM, and former director, Monsanto Research Center; Prof C Kameshwar Rao, consultant-biotechnology and medicinal plants, Foundation for Biotechnology Awareness and Education; Dr P Balasubramanian, former head, Department of Biotechnology, Center for Plant Molecular Biology; and Dr Seetharam Annadana, technology lead - Vegetables, Syngenta India participated in the workshop.

The workshop concluded that the Ministry of Environment and Forests (MoEF) was strongly influenced by those opposed to agricultural biotech than by credible, critical and balanced scientific judgments. There was a consensus among the scientists that the seven city public consultation by MoEF did not provide an adequate opportunity for the scientific community to voice its concerns.

A petition to the ministries and concerned departments of the government was also drafted after considering the opinions of all the participants. The memorandum was submitted to Prime Minister, Ministries for Agriculture, Science and Technology, Human Resource Development, Environment and Forests, Health and Family Welfare, Commerce, and also the Indian Council for Agricultural Research, Department of Biotechnology, Department of Science and Technology, Department of

Scientific and Industrial Research, Indian Council for Medical Research and Council for Scientific and Industrial Research.

The scientists also called upon various government regulatory agencies to step in and support the demand of ending the moratorium at the earliest. They also emphasized on public awareness as an important aspect of the technology development.

India contributes 20% to generics market

Indian pharma market has registered 38,692 crore ($8.25 bn) in 2009 and has enjoyed double-digit growth in the past five years, peaking at 25 percent in 2007. The strong growth registered by the Indian economy has helped to drive its pharma market and industry. India's expanding middle class, with growing affordability and greater access to healthcare are the main drivers for the current growth of the industry and economy.

As per PriceWaterhouseCoopers report, finished generics supplied from India account for 20 percent of the global generics market. It is estimated that 70 percent of the patients belong to 87 developing countries and received drugs produced in India and distributed by the UNICEF, International Dispensary Association, the Global Fund and the Clinton Foundation.

Biocon signs supply pact with Optimer

Biocon has signed a long-term agreement with US biopharma company, Optimer Pharmaceuticals, for the commercial manufacturing of active pharma ingredient, OPT 80.

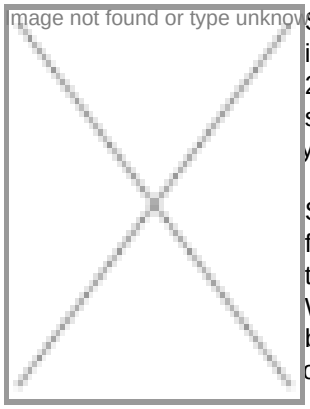
The drug is among a new class of macrocyclic antibiotics and is being developed by Optimer to treat serious colon infections such as Clostridium difficile infection and is expected to be commercialized soon. For the last five years, Biocon has been an important partner in Optimer's Opt 80 development program and will continue this relationship with the manufacturing and supply of this product once the drug gets the approval.

Antibiotics market registers 3,250 cr

Changing trends and development in healthcare infrastructure make way for wide range of new antibiotic entrants in the Indian pharma market. According to a report by Datamonitor titled, 'High-end antibiotics usage in India,' the market for high-end antibiotics in Indian hospitals registers 3,250 crore ($686 mn) in FY 2010, having shown an year-on-year growth of 49.8 percent. The market is estimated to grow to about 8,725 crore ($1,841 mn) by FY 2015, posting a CAGR of 21.8 percent.

Datamonitor noted that as healthcare infrastructure improves in India and well-established hospital chains expand their presence across the country, the market for hospital antibiotics is likely to widen. Although the anti-bacterial market in India is currently dominated by generics, newer antibiotics are constantly being sought after.

Serum launches indigenous intra-nasal swine flu vaccine Nasovac



Serum Institute of India (SII), one of the largest vaccine manufacturers in India, has launched its indigenously developed intra-nasal H1N1 vaccine under the brand name Nasovac on July 14, 2010, in Mumbai. SII thus became the third manufacturer in the country to market vaccines against swine flu, the other two companies being Zydus Cadila (VaxiFlu-S) and Sanofi-aventis (whose y the Indian government).

Speaking at the launch of the product Adar Poonawalla, executive director of SII, said, â€œThe fear of the public about the pandemic last year was a challenge for our healthcare system. In India, there are around 150,000 child deaths due to vaccine preventable diseases. According to the World Health Organization (WHO), even the African nations and other third world countries have better immunization programs than India. The Government of India and the Ministry of Healthcare ources and funds. India as a nation is not bothered about healthcare.â€?

A Live attenuated influenza vaccine (LAIV), Nasovac, is a single dose vaccine fitted at the top of the syringe and around 0.25 ml is to be administered in each nostril, mimicking the path followed by the virus to enter the body. The vial consists of five doses. Except for pregnant women, any individual above the age of three years can use this intra-nasal vaccine. On the other hand, an injectable vaccine can be administered only for individuals 18 years and above.

LAIV has the upper hand over an inactivated-based vaccine in many respects. Dr Prasad Kulkarni, additional medicaldirector of SII, said, â€œIn the case of a LAIV, the production capacity is 10 times higher than inactivated-based vaccines, making this suitable during the times of a pandemic. The production cost is much lower and this enables us to produce larger

capacities of the vaccine. Plus the simplicity of the nasal route is an added benefit.â€?

With the outbreak of swine flu pandemic last year, Serum Institute was one among the three Indian vaccine makers-along with Bharat Biotech and Panacea Biotec-provided with the swine flu virus strains by the WHO to develop the vaccine. It was indeed a battle against time for the team. A BioSafety Level 2 (BSL 2) facility was set up a few weeks post the outbreak was officially termed as a pandemic.

The seed virus was supplied by the WHO to SII and phase I trials of the Nasovac was conducted on 50 healthy people, post approval by the Indian regulator, the Drug Controller General of India (DCGI), around 330 volunteers (both adults and children) were roped in for phase II trial. According to FDA norms, trials cannot be conducted on pregnant women, hence the vaccine was tested on pregnant rats to prove its safety and efficacy.

The product is now priced at half the price of similar vaccines marketed by Indian and foreign companies. â€œThe price of a single dose of this vaccine will cost Rs 160 ($3.42) and is now available at retail outlets across all cities in India. As of now, we will market the product in India,â€? said Poonawalla. The company is slated to receive the WHO pre-qualification in a few months, subsequent to which it intends to market the product in 100 countries.

DBT all set to strengthen biotech R&D in NE states

While initiating a special program for the north eastern states, the Department of Biotechnology (DBT), Government of India, has invited proposals in the field of basic and applied biotechnology from Indian scientists, working on a regular basis in universities, academic, medical or research institutions in any of the north eastern states of India in collaboration with scientists from other national institutions.

The scientists should be working in any of the broad areas of health sciences, agricultural sciences, veterinary sciences, pharmaceutical sciences, biomedical engineering, bioinformatics, food and nutrition, healthcare including alternative medicine, nanotechnology and environmental biotechnology.

The joint R&D programs may involve partners from recognized private institutions as well as NGOs. The program aims to help establish and strengthen R&D activities in the north eastern states like Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura; through joint ventures.
The proposals will be evaluated by the committee of experts. The approved projects would be initially funded for a period of three years that may be extended based on the performance review. The information in the application should be clearly given in two parts - one, pertaining to the parent institution in the north eastern region and the other regarding the collaborating institutions. The last date for sending the proposals as per the DBT format has been kept as August 9, 2010.