

BioPharma

Wockhardt, Ranbaxy in race for AIIMS typhoid technology

Indian Pharma major Ranbaxy and Wockhardt are the two bidders apart from other short listed by Biotech Consortium India Ltd (BCIL) to acquire a blockbuster typhoid recombinant vaccine technology developed by the All India Institute of Medical Sciences (AIIMS), New Delhi. The project was assigned by the department of biotechnology (DBT) and is due for commercialization. Other technologies developed by AIIMS so far include DNA/ MVA based-HIV -I kit, JEV chex- a rapid detection kit for Japanese Encephalitis etc.

The typhoid vaccine market in India is estimated to be around \$5.6 million to \$6.8 million (Rs 25-30 crore) with an 80 million doses per annum requirement and export potential of \$1 billion at the current price level. Currently, the vaccine is an optional vaccine both for children and adults and the government is likely to include it in the immunization program.

DRL launches 'Shadowz' SPF protection sunscreen

Dr. Reddy's has launched 'Shadowz' a sunscreen in a gel form which offers high SPF protection for patients prone to or suffering from melasma and photo dermatitis. Shadowz effectively prevents damage from both UV-A & UV-B spectrum of UV radiation. Being transparent it will not leave any opaque residue; hence being more acceptable cosmetically. It is entirely free from comedogenic chemicals (like PABA) or substance, which can cause allergic reactions (like paraben). The prescription sunscreen market is estimated at \$ 2.95 million (Rs.13 crore) and growing at a rate of 14.30%.

Aurobindo Pharma products in WHO list

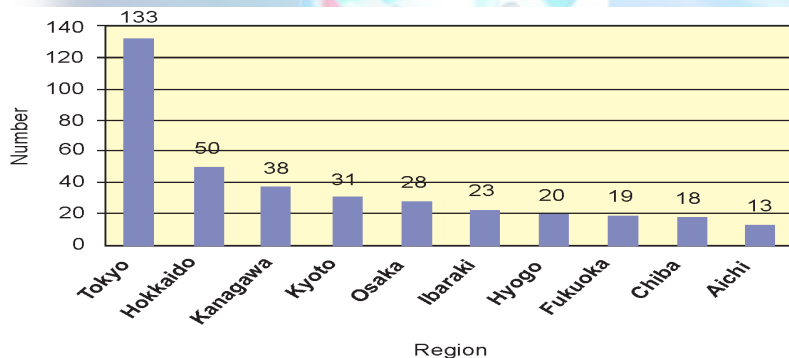
The World Health Organization (WHO), Geneva, has included Aurobindo's three products: **Zidovudine(300 mg)** , **Lamivudine tablets(150 mg)** and **Lamivudine tablets(300 mg)** in its pre-qualification list. All the three products form part of Anti Retrovirals (ARVs), which help Aids/HIV affected countries to provide cost effective

Indian drug companies to tap \$90 billion Japan market

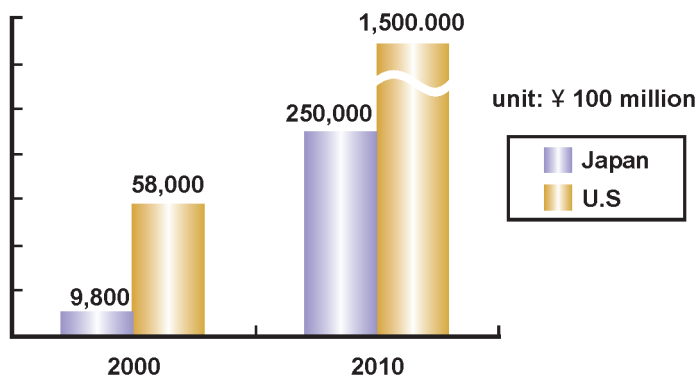
After expanding into the US and Europe, Indian drug companies are heading Japan, the second largest Pharma market. Indian Pharma companies are facing heat in the US in the wake of higher drug prices. Japan seems to be an attractive option. The Japan market is estimated to reach ¥25 trillion by 2010. The number of applications for patents of genome- related technologies in Japan is the fourth largest, following US, China and Europe in 2003. The number of bio-venture rose approximately to 400 in 2004 from 304 in 2001.

Indian drug companies are using the mix strategy of takeovers, alliances and regulatory fillings to enter Japanese market which is a hard market to crack. Leading the race are the drug majors such as Ranbaxy, Lupin, DRL and Orchid chemicals. Ranbaxy is firming up a plan to launch its key products with a joint label arrangement with Japanese drug maker Nikon Pharma. Under the agreement, Ranbaxy would be marketing its top-end generic versions in Japan with the aid of local partner. Similarly, Lupin has reportedly struck an alliance with local drug major Kyowa to develop and market new drugs. As per the deal, Lupin would develop new generic versions of blockbuster off patent drugs while the Japanese company would take care of the marketing aspect. Orchid chemicals are mulling options to enter the market. The entry barrier is tough including the regulatory hurdles.

2004 Region Wise Bio-Venture in Japan



Projection of Japanese and US Biotech Markets



Source: Japan Patent Office.

treatment. The global fund to fight AIDS, Tuberculosis and Malaria disburses money for medicines that have been pre-qualified by the WHO process

Morepen files 52 DMF

Morepen Laboratories has filed 52 DMF (Drug Master File) across 10 European countries for six products. The filings are for cholesterol-reducing drug Atorvastatin for both the amorphous and the crystalline forms, anti-asthmatic drug Desloratadine, anti-diabetic drug pioglitazone and antibacterial drugs Sultamicillin Tosylate and Sultamicillin Base. Morepen expects its European market share to go over 20 per cent over the next three years.

Unichem launches Zyncet

Unichem launched its first product Zyncet tablets, in anti-histamine therapy in South Africa. Unichem is in the process of launching the first Ayurvedic anti-arthritic agent named Artrex capsules & cream. Unichem has also received product registrations for Domadol & M-Cam in pain management and Trizac in Neuropsychiatry, due for launch in the coming months.

BioServices

J&J to conduct clinical trials

JOHNSON & JOHNSON (J&J) is planning to conduct clinical trials of its new dapoxetine hydrochloride drug in India for premature ejaculation. J&J has submitted the drug to USFDA for approval. The patent for dapoxetine was originally held by Eli Lilly and was bought by PPD, Inc (a research organization) in 2003. PPD then licensed the drug to ALZA Corp, a subsidiary of J&J.

Glenmark's asthma drug gets nod for further trials

Glenmark's asthma molecule GRC 3886 received approval to conduct further clinical trials from the US regulatory authorities. Phase II trials is expected to begin by early 2006 in the US. GRC 3886 has also been granted its International Non-proprietary Name Oglemilast by a World Health Organization body that controls the grant of 'generic' names to new experimental drugs.

Drugs price control

The Prime Minister's task force has identified cancer, HIV/AIDS, diabetes, cardiovascular diseases and costly antibiotics as the broad segments where the government should have a control over the drugs price. The task force is now evaluating what criteria the government should apply on these therapeutic classes with large number of drugs so as to zero in on specific products for price controls. The panel is exploring if the price control filter it had identified in the yet-to-be-implemented '02 drug policy could be applied to select the drugs. It identifies a drug for price control based on the mass consumption nature and the absence of market competition. The '02 policy says, if the total moving average total (MAT) value of any particular key ingredient of a drug (called the bulk drug) is more than \$5.7 million (Rs 25 crore) and the market share of any of the formulators is 50% or more, then the drug should be under price controls. Besides, if the MAT of any particular bulk drug is less than \$5.7 million (Rs 25 crore), but more than \$ 2.2 million (Rs 10 crore) and the market share of any of the formulators is 90% or more, then the price of the drug should be controlled.

Another alternative the task force is contemplating is applying the criteria on all the 354 essential drugs the health ministry has identified to filter out the key ones. The task force, which is to finalize its report shortly, will also recommend setting up a committee to negotiate prices of patented drugs before marketing nod is given.

Bio-Manufacturing Consolidates

While Indian companies are making significant investments to improve and expand their manufacturing facilities in order to enter regulated markets, global players are eyeing India to set up their manufacturing bases in the country. Indian manufacturing matures complying with global standards. Today many companies in India and elsewhere are planning to make significant investments in R&D and manufacturing.

It is not just the biopharma companies which are building quality facilities. Several other biotech manufacturers like those in the enzymes sector are building newer facilities. CL Rathi, managing director, Advanced Biochemicals Ltd, Mumbai which has been manufacturing and exporting cellulase enzyme for the last nine years manufacture about 1000 MT (metric tons) cellulase enzyme per year. It is also planning to set up a 100 percent Export Oriented Unit and invest over Rs 110 crore at Indore SEZ to manufacture cellulase, alkali protease, amylase, catalase, xylanase, acid and neutral protease enzymes.

Similarly, Maps India Ltd, a biotechnology company producing enzymes and microorganisms, has signed a MoU with the government of Gujarat for investing Rs 10 crore for production of new enzymes and microorganisms during the current year. Celestial Labs is investing close to Rs 15 crore to set up an enzymes production unit in Hyderabad.

Bharat Biotech, Biocon, Intas Pharmaceuticals, Shantha Biotechnics, and Wockhardt are some of the companies that are manufacturing rDNA products in India. Others like Glenmark Labs are serious on setting up manufacturing

Phase II studies in the US would be conducted by Forest Laboratories, Glenmark's development partner for Oglemilast in North America. Oglemilast is being tested for asthma and COPD and had successfully completed Phase I single and multiple dosing studies in the UK in March 2005. Glenmark is now evaluating similar partners to take Oglemilast forward in the European market and expects to finalize a partner by March 2006

Manipal AcuNova opens new drug research center

The Manipal group company AcuNova has launched AcuNova KH clinical research center in Udupi district for undertaking generic drugs, NDDS and NCE research. The clinical research services in the centre will include pre-clinical studies, bio-availability, bio-equivalence, pharmacokinetics and data management in areas of oncology, infectious diseases, endocrinology, neurology and dental sciences.

Alliances

Biocon collaborates with Nobex

Biocon and North Carolina's Nobex Corporation entered into research collaboration to develop an oral peptide product for the treatment of cardiovascular diseases. Both the companies also plan to advance the oral human brain-type natriuretic peptide (hBNP) programme towards an IND (Investigational New Drug filing with the FDA (US Food and Drug Administration) in 2007 and clinical trials beginning later that year.

The intent of an oral hBNP would be to have a product available for chronic use, rather than only for acute use for a number of potential indications, including early-stage heart failure patients. hBNP is an endogenous peptide produced by the heart under both physiological and pathological conditions, such as ischemic stress or blood volume overload. hBNP has multiple biological activities (through natriuretic, diuretic, vasorelaxant, and lusitropic properties) that contribute to its therapeutic use in treating heart failure.

facilities for recombinant biotech products. Haffkine BioPharmaceuticals, Hindustan Antibiotics, Shreya Life Sciences, and US Vitamins have been into formulation business so as to produce for mass consumption.

Multinationals also are now actively pursuing their plans to have manufacturing facilities in India. On February 22, 2005, Glaxo SmithKline (GSK), commenced work to set up a vaccine filling and packing unit for vaccines intended for India at Nasik. And it is expected to be fully operational by early 2006. Chiron Behring Vaccines Pvt Ltd, a wholly owned subsidiary of the Chiron Corp., has a manufacturing facility at Ankleshwar in Gujarat. The plant is based at the manufacturing complex of Aventis Pharma another major pharma company in India with which Chiron has a manufacturing agreement.

Sigma-Aldrich Corporation, the US-based \$1.2-billion leading life sciences and high technology company and German pharmaceuticals and chemicals giant Altana AG are planning to set up facilities at SP Biotech Park, Hyderabad. UK-based Radox Laboratories would set up a diagnostics kit manufacturing unit in Bangalore.

India is now emerging as a favored destination for several reasons. During the last two decades, India has emerged as a preferred destination for cost competitive quality production of pharmaceutical API (active pharmaceutical ingredient) and formulations. Today, India enjoys the distinction of having the maximum number of US FDA approved facilities anywhere in the world outside of the US and has proven its claim to be a major manufacturing hub and supply center to the world. With the Indian IPR laws in place, the pharma manufacturing sector is expected to leap. Indian biopharmaceutical industry is moving up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented global presence, providing wide range of value added quality products and services.

Globally there is an acute shortage of bio manufacturing capacity. Indian biopharmaceuticals can provide the manufacturing services as it has good manufacturing infrastructure for production of biotech products that would meet the global standards in terms of quality. The government support to the companies interested in setting up manufacturing facilities, by offering incentive package as being offer for R&D activities will be very helpful echoes the industry.

Ranbaxy to challenge Pfizer

Indian Pharma major, Ranbaxy has launched court battles in Britain and US against the American pharmaceutical giant Pfizer for the rights to produce the cholesterol drug Atorvastatin at a cheaper price. The move is to save the National Health Service billions of pounds a year. Ranbaxy is trying to invalidate Pfizer's patent, taking away its exclusive right to sell the drug, and market it itself in Britain and America. There are highly complex arguments involving the chemical structure of the drug and the legal history of all patent claims.

Grandix Pharma ties with Chromogenix

THE Chennai-based Grandix Pharmaceuticals Ltd has tied up with Chromogenix, Italy - a group company of one of the world's largest diagnostics major Instrumentation Laboratory Inc - to market chromogenic substrates in India. Grandix will market Chromogenic substrates with a portfolio of more than 70 products in the field of coagulation and fibrinolysis throughout India. Chromogenic substrates are used widely in Pharma and R&D labs, biotechnology companies, blood banks, clinical laboratories and hospitals.

News & Awards

Maharashtra government to promote bio-diesel

The Maharashtra government has announced non-conventional energy policy that will greatly benefit bio-diesel growth. Under the policy, land would be made available for non-conventional energy projects at low rates. Jatropha plant from which bio-diesel is produced would be promoted on a large scale and its cultivation would be encouraged in the State. The state is also planning to set India's first bio-fuel park.

Ranbaxy US arm gets award

Ranbaxy Laboratories Ltd's wholly owned subsidiary, Ranbaxy Pharmaceuticals Inc (RPI), USA, has received the Supplier Quality Award from Cardinal Health. Cardinal Health is the second largest wholesaler in the US, which supports over 31,000 pharmacies throughout the country. Earlier in June this year, RPI had also received the prestigious Supplier Award from Wal-Mart for outstanding performance in the first quarter of 2005.

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Research Report

The Advisory services will offer customised reports on the biotechnology sectors. Below are the contents of few sample reports.

Indian Pharma: Out-Licensing Deals

1. Out-Licensing Overview
2. 2001 - 2005 details
3. Future deals

BioIndustrial

1. Global scenario and India position in global front
2. Indian BioIndustrial Market size
3. Sales of various product categories
4. Indian players and MNCs in India and their strategic positioning and market shares.
5. Manufacturing capabilities and capacities of companies in India
6. Business issues in the sector, which include the incentives being offered along with custom duties and excise and other related issues that impact the business
7. Attractive places(clusters) to set up shop in the country
8. Future outlook
9. Opportunities and challenges
10. Financing options

BioAgri

1. Global scenario and India position in global front
2. Indian BioAgri Market size
3. Major players
4. Bt cotton approvals, varieties and current trend in Bt cotton
5. Mergers in the sector
6. Companies producing Biofertilizers/Biopesticides
7. Key concerns and issues
8. Government role and policy framework

BioTech Parks

1. Punjab
2. Rajashtan
3. Lucknow
4. Mumbai-Pune
5. Gujarat
6. Bangalore
7. Features and incentives offered by the respective parks

