

BioBusiness in India

Neotia University (India) signs MoU with Frost & Sullivan Inc. to partner in two areas – developing biotech parks in West Bengal and establish entrepreneur parks. Parks will vary in size from five to 25 acres, and investment may range from USD \$50 MIL to \$350 MIL. *Source: Economic Times, Apr 22 2016*

Pharmexcil (Pharmaceutical Export Promotion Council of India) will sponsor an India Pavilion at the Korea Pharm, Kingtex, Goyang, South Korea from April 26-29. The country looks to venture into unexplored Asian generic markets including Korea, Japan and South East Asia. *Source: Pharma Biz, Apr 21 2016*

India's Union Minister for Science and Earth Sciences recently inaugurated Biotech Infrastructure Facility at ICAR-National Research Centre on Mithun at Jharnapani, Medziphema. The facility was funded by the Department of Biotechnology, Govt. of India. *Source: Nagaland Post, Apr 18 2016*

Proteomics International Laboratories Ltd (PILL) looks to expand its operations into India. The co. will conduct a trade visit in April to look at its biosimilars analytics and biomarker services. The co. has been operating in India since 2004. *Source: Proactive Investors, Apr 14, 2016*

India and Belgium look to finalize a MoU between the Department of Biotechnology of India and the Research Foundation - Flanders for future partnerships in India's biotechnology sector. *Source: The New Indian Express, Apr 26 2016*

India and the European Union recently signed the 'EU-India Agenda for Action 2020', a strategic partnering action plan for the next five years. The agenda will look address key issues including the current EU import ban against more than 700 generic drugs clinically tested by Hyderabad-based GVK Biosciences. The action plan will also coordinate possible regular meetings of the EU-India Joint Working Group on pharmas, biotech and medical devices. *Source: Business Standard, Apr 1 2016*

India's govt. has begun a joint action plan to help the biotech sector reach USD \$100 billion by 2025. The govt. is working to strengthen the bio-cluster ecosystem across the country; and looks to create the Bengaluru-Boston biotech corridor. *Source: The Pharma Letter, Mar 29, 2016*

Govt. of India's Ministry of Science & Technology, Department of Biotechnology under its Biotech Labs at Senior Secondary Schools (BLISS) program for North Eastern states of India established its first biotech lab at the Mayangnokcha Govt. Higher Secondary School in the Mokokchung district. *Source: The Morung Express, Mar 30 2016*

India's govt. established the Regional Center for Biotechnology, located in the northern state of Haryana that will help promote R&D in South Asia, and the Asian region. No funding details available. *Source: Business Standard, Apr 26, 2016*

Govt. of India recently established the Advanced Bio-Chemistry Immunoassay Laboratory in the Government Medical College, Jammu. The lab. will be used to conduct hormone analysis, cancer marker detection, allergy tests, tests of detection of early onset of septicemia in critically ill patients along with detection of antigen and antibodies against various disease causing agents. *Source: Rising Kashmir, Apr 26 2016*

BioScience in India

Bharat Biotech announced it has two vaccine candidates against the Zika virus that will be soon entering pre-clinical trials in animals *Source Science Alert, Feb 8 2016*

Several key Indian drug makers, including Aurobindo Pharma, Serum Institute of India and Panacea Biotech are currently backing or working on research into pneumonia vaccines in India. *Source: Various, Mar 30 2016*

A computational neuroscientist, Dr. Shyam Diwakar, Lab Director of Computational Neurosciences and Neurophysiology at the School of Biotechnology of Amrita University in Kollam, Kerala, recently developed a computer model to understand brain disorders. The model will be used to help understand cancer, its origin and functional misbehavior and even infections spread through viruses, and to help aid creating tailor-made drugs. *Source: The Times of India, Apr 9 2016*

Govt. of India recently introduced the rotavirus vaccine Rotavac into the official immunization program. This completes a 30-year development in Delhi's All India Institute of Medical Sciences in 1985, and will be marketed by Bharat Biotech. *Source: Various, Mar 28 2016*

A group of Indian researchers recently found that the proportion of people 'living with HIV in a population who have a detectable viral load is much more strongly associated with the rate of ongoing HIV infection in that community (HIV incidence) than the average viral load in people living with HIV (community viral load)', according to a recent study. The researchers used an incidence assay to determine which measure of viral detectability had the best correlation with incidence. *Source: AidsMap, Apr 6 2016*

Indian scientists at the Indian Institute of Science recently developed the 'Multiple Analyte,' a hand-held device that can conduct eight biomedical tests. *Source Bangalore Mirror, Apr 1 2016*

Pfizer looks to use its latest European approval for multi-dose vials of pneumococcal vaccine Prevnar 13 in the Indian market. The president for Pfizer's global vaccines operations recently stated 'if Prevnar 13 is to be included in the Indian NIP (National Immunization Program), the company will be keen to work with the Indian govt. to ensure that the multi-dose vial is introduced as soon as possible to help protect the children from pneumococcal disease.' The co. is talking with health officials to request an accelerated review process for the vaccine in the new pack, which may be as early as end of the year. Pfizer stated the vials are laced with a preservative, can be used for four doses and is to be priced at \$3.1 for each shot under the Global Alliance for Vaccine and Immunization Advance Market Commitment program. *Source: The Economic Times, Apr 7 2016*

Seven states in India will administer an injectable polio vaccine into babies' skin layers to induce protection against Polio. The states account for 35% of the country's population. At this time, only the Bacillus Calmette Gurrain vaccine, used against childhood tuberculosis, is administered through an intradermal route. *Source: The Times of India, Mar 29 2016*

Regulatory and Clinical in India

Biocon recently became the first Indian co. to receive regulatory approval for a biosimilar insulin in Japan. This approval will enable the company to export Glargine, a biosimilar insulin in a disposable pen to Japan for treatment of diabetes. The co. will partner with FUJIFILM Pharma Co Ltd to launch the product. *Source: Financial Express, Mar 29 2016*

Delhi's High Court recently issued new guidelines in its latest interim order involving Roche's breast cancer drug Trastuzumab sold under the brand name Herceptin. In the order the Court will allow co.'s like Biocon, Mylan and Reliance Life Sciences to sell their versions of the biological breast cancer drug Trastuzumab, but disallowed them from claiming it is a bio-similar version of Roche's Herceptin. The court also issued additional guidelines for the defendants. *Source: The Hindu Business Line, Apr 26 2016*

Members of the Indian govt. requested again for the Govt. to put together a strong regulatory framework on research and innovations in the areas of biotech as soon as possible. They urged the govt. to revive the Biotechnology Regulatory Bill which lapsed in 2013, and stated Indian innovators and scientists are hurting due to India's trade related laws not in agreement with Trade Related Intellectual Property Rights. *Source: Web India 123, Apr 25, 2016*

Govt. counsel continues its argument at the Delhi High Court stating pharma co.'s have long used India as a dumping ground for irrational fixed dose combo drugs rejected by other countries. Arguments between the Center and several drug makers who oppose the ban implemented on their brands last month is set to continue as the court extended its interim relief for four more days. *Source: The Economic Times, Apr 19 2016*

India's Department of Pharmaceuticals Secretary recently stated Indian drug control as the 'weakest in the world', and argues that the industry has many issues and non-cooperative departments. *Source: DNA India, Apr 20 2016*

India will begin to administer a bivalent Oral Polio Vaccine (OPV) in its govt. immunization services. The timing of the doses will be the same for children currently using the trivalent OPV. *Source: The Hitavada, Apr 21 2016*

Dr. Reddy's chairman recently blamed U.S. FDA inspections for hurting Indian drug exports at a Board of Trade meeting in New Delhi. FDA has begun stepping up enforcement of Indian manufacturing sites, and has sent multiple warning letters to firms with Indian facilities over the past year. *Source BioPharma Dive, Apr 7 2016*

Central Research Institute established its first Current Good Manufacturing Practice (cGMP) compliant facility in Himachal Pradesh for the production of vaccines for the universal immunization program. The facility will be used to manufacture DPT and TT vaccines. *Source: Various, Apr 25 2016*