

BioBusiness in India

Cipla Ltd. will build a USD \$89 MIL biosimilars manufacturing facility in South Africa, with this the co.'s first manufacturing facility outside of India. *Source: The Economic Times, June 8, 2016*

Shantha Biologics, Sanofi Pasteur, opened its new USD \$818.7 MIL vaccines manufacturing facility near Hyderabad. Products include pediatric pentavalent vaccine against diphtheria, tetanus, pertussis, Hib and hepatitis B. *Source: BioPharma Dive, June 2, 2016*

The Delhi High Court issued an order that Biocon, Mylan and Reliance Lifesciences cannot refer to their trastuzumab "similar biologic" (marketed as CANMAb; Bmab-200; Hertraz) as being a biosimilar version of Herceptin from Genentech/Roche. *Source: Hindu Business Line, April 26, 2016*

Reliance Life Sciences has full rights to the infliximab (Remicade) biosimilar that had been in development by Epirus before it went bankrupt. *Source: Pharmaceutical Manufacturing, July 28, 2016*

Lupin Ltd. plans further expansion in the U.S., including acquisitions. The U.S. is currently the co.'s largest market, with Lupin the 5th largest generic drug company in the U.S. *Source: International Business Times, May 2, 2016*

India will be successful in entering Intl biopharma markets, with biosimilars a "perfect fit", according to a new Frost & Sullivan White Paper. *Source: PRNewswire, June 2, 2016*

Indian exports of finished drugs will decline 10%-12% annually over the next 5 years in terms of revenue. This compared with up to 19% annual growth in the last decade, largely due to increased competition in the U.S. market, according to Crisil Research. *Source: IndiaToday, May 17, 2016*

Fosun Pharmaceutical Group, Shanghai, China, purchased 86% stake in India's Gland Pharma for USD \$1.35 BIL. *Source: Co News, July 29, 2016*

Biocon plans to file for U.S. approval of 4 biosimilar products – versions of insulin glargine (Lantus), trastuzumab (Herceptin), pegfilgrastim (Neulasta) and adalimumab (Humira). *Source: FiercePharma, June 1, 2016*

Neotia University, West Bengal, concluded an agreement with Frost & Sullivan Inc. to collaborate in setting up biotech parks in India and promoting entrepreneurship. *Source: Business Standard, April 22, 2016*

India-based “buyers clubs” are increasing, with Americans purchasing cheap pharmaceuticals, such as for hepatitis C and biopharmaceuticals, in India, with these either mailed to them or traveling to India to receive their drugs. *Source: CNNMoney, June 2, 2016*

India imported USD \$2.22 BIL in drug APIs in 2015, up from \$2.11 in 2014, but with the country trying to reduce API imports, ≥80% of which come from China. *Source: International Business Times, May 3, 2016*

BioScience in India

Indian chapter of the Parenteral Drug Association cited the shortage of skilled parenteral drug workforce as the greatest handicap faced by the Indian pharma industry. *Source: Hindu Business Line, May 6, 2016*

Researchers at Rabin Medical Center in Petah-Tikvah, Israel, reported that U.S. consumers pay the highest costs for pharmas, while pharmas are least affordable in India and China, now the source for most drugs. Drugs were most affordable in Australia. *Source: Reuters, June 6, 2016*

Regulatory and Clinical in India

Central Drugs Standard Control Organization, which worked with the Department of Biotechnology, proposed new guidelines concerning waiving (not requiring) late-stage trials where products are already approved in highly-regulated markets. *Source: FiercePharma, July 5, 2016*

Prime Minister Narendra Modi stated the Union Cabinet abandoned updating the Drug and Cosmetics Act of 1940 in favor of a rewrite to better include new regulations concerning biopharmas, cell therapies and clinical trials. *Source: In-Pharmatechnologist.com, June 23, 2016*

U.S. Trade Representative's (USTR's) Special 301 report continues to put India on its 'Priority Watch List' for its intellectual property rights (IPR) regime. *Source: IP-Health, April 29, 2016*

Central Research Institute established India's first Current Good Manufacturing Practice compliant facility for the production of vaccines for universal immunization program vaccines manufacture. *Source: Domain-b.com, April 25, 2016*

India's parliament funded a Regional Centre for Biotechnology in Faridabad, Haryana. The center will also offer Masters and Ph.D. degrees. *Source: General Knowledge Today, July 19, 2016*

Daiichi Sankyo, Japan, received a USD \$400 MIL award from two leading Indian investors related to deception involving the company's acquisition of Ranbaxy, including non-disclosure of manufacturing problems and failures. *Source: Wessex Life Science Cluster, May 5, 2016*

RPG Life Sciences Ltd., Mumbai, a formulation specialist co. sold its biotech unit to Intas Pharmaceuticals Ltd for USD >\$3.7 MIL. *Source: Deal Street Asia, May 27, 2016*

Drugs Controller General India granted limited approval to Stempeutics' allogeneic stem cell product, Stempeucel for the treatment of Buerger's Disease, with this the 1st off-the-shelf stem cell product approved in India. *Source: BioPharma-Reporter.com, June 1, 2016*

Serum Institute of India is suing two former employees for theft of vaccine-related intellectual property and filing related patents for another co. *Source: The Indian Express, May 9, 2016*

The Subject Expert Committee, Drug Controller General of India did not support an application by Sanofi to conduct clinical trials with a

new dengue vaccine, Dengvaxia, in India. *Source: Economic Times, May 5, 2016*

Central Drugs Standard Control Organization is sending staff to drug manufacturing hubs across the country to train manufacturer staff in good manufacturing practice in hopes this will get to the root of problems in record keeping and quality control.

Source: FiercePharma, May 18, 2016

Commerce and Industry Ministry is conducting a study to measure the impact of foreign investment on the pharma industry. The results will be controversial, whether they seek to encourage or reduce foreign investment. *Source: FiercePharma, May 30, 2016*

India's govt. will be funding six bulk drug and three medical device "parks" to encourage domestic manufacture rather than imports. The parks will include common utilities, centralized storage, testing labs, IPR management, facilities design, and guest accommodations.

Source: Economic Times, June 5, 2016

Hilleman Laboratories, New Delhi, started Phase I and II trials with a combined heat-stable rotavirus vaccine and cholera vaccine. *Source: The Economic Times, April 27, 2016*