



**News Updates: January 16, 2014**

#### FDI

**Publication: The Financial Express**

**Edition: National**

**Date: January 16, 2014**

**Headline: [Column: Need to look beyond non-compete clause](#)**

**Synopsis:** The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry has recently announced that the existing foreign direct investment (FDI) policy in the pharma sector will remain unchanged, except with a condition that the non-compete clause will be permitted only as an exception, with prior approval of the Foreign Investment Promotion Board (FIPB). The decision will, hopefully, keep the spirits of the foreign investors intact while protecting the interest of domestic players. The decision to maintain the status quo on FDI caps will send a message to the international investor community that India has stable FDI policies—after all, a perception of an unstable policy environment will affect the decision of any investor in committing large funds. Whether the protection provided to the domestic pharma manufacturing companies will be as effective as anticipated or not will be clear only after the implementation of the policy. However, it is important to understand the broad contours of the non-compete clause and its implications, especially for the pharma sector.

#### Clinical Trials

**Publication: The Economic Times**

**Edition: National**

**Date: January 16, 2014**

**Journalist: Divya Rajagopal**

**Headline: [Drug watchdog wants mandatory recording of clinical trial consent](#) (Online Headline: DCGI wants mandatory recording of clinical trial consent)**

**Synopsis:** The Drug Controller General of India (DCGI) has released draft guidelines that make it mandatory for clinical research organisations to conduct an audiovisual recording of the trial patients informing them about each and every risk involved while undergoing the trial. The measure, introduced in addition to the existing written consent forms, could bring in greater transparency and clarity in clinical trials. According to the draft guidelines issued by the drug controller in response to a Supreme Court directive, this norm will also apply to the global trials conducted in India. In case the trial patient is not able to give informed consent, the investigators have to take the consent of a legally representative person.

#### FDA / Drug Regulatory / DCGI / Pharma Policy

**Publication: Mint**

**Edition: National**

**Date: January 16, 2014**

**Journalist: Vidya Krishnan**

**Headline: [Direct donor-patient blood transfusion to be legalized](#)**

**Synopsis:** In a major step to address the shortage of blood in India, the Drug Technical Advisory Board (DTAB) will on Thursday legalize the direct transfer of blood to a patient from a suitable donor in India. At present, the Drugs and Cosmetic Rules (1945) authorize collection of blood only by licensed blood banks, in effect making the so-called unbanked directed blood transfusion (UDBT) illegal. But India has only 2,545 licensed blood banks, most of which are in the cities, a factor that plays a huge role in the deaths of

pregnant women and road accident victims, according to health activists and rural surgeons who have been campaigning for legalizing UDBT. Drug Controller General of India (DCGI) G.N. Singh confirmed the decision.

**Publication: The Times of India**

**Edition: Kochi**

**Date: January 16, 2014**

**Headline: [Government can prosecute offenders, rules HC](#)**

**Synopsis:** The government has the right to prosecute manufacturers and dealers of dietary supplements if they violate provisions of Drugs and Cosmetics Act, and no other option is available as per law to prove innocence other than facing prosecution, the Kerala high court held. A division bench comprising Justices Thottathil B Radhakrishnan and P Ubaid gave the ruling after considering a batch of petitions questioning prosecutions initiated by drugs inspectors alleging violation of provisions of Drugs and Cosmetics Act of 1940 (DC Act). The petitions filed by manufacturers, distributors, and dealers of dietary supplements said their articles are essentially food items and not drugs as defined in the Act. Some of them also argued that they are operating after obtaining statutory licences of different states under the provisions of Prevention of Food Adulteration Act of 1954 and the Food Safety and Standards Act of 2006.

**Publication: Pharmabiz**

**Edition: Online**

**Date: January 16, 2014**

**Headline: [Pharmacists want regulators to strictly implement Schedule K \(5\) of D&C Act](#)**

**Synopsis:** Pharmacists across the country want the drug regulators to take a uniform stand while ensuring the implementation of different provisions of the Drugs and Cosmetics (D&C) Act. This demand comes in the wake of rising frustration among the pharmacy community over the two faced approach the drug regulators have been displaying while implementing Schedule K, which deals with monitoring and controlling the practice of registered medical practitioners engaged in stocking and dispensing of medicines directly to the patients without licence.

## General Industry

**Publication: Business Standard**

**Edition: National**

**Date: January 16, 2014**

**Journalist: Sushmi Dey**

**Headline: [Ranbaxy in tie-up to source raw material for Diovan](#)**

**Synopsis:** Drug maker Ranbaxy Laboratories is learnt to have partnered another multinational pharmaceuticals company for sourcing active pharmaceutical ingredients, or API, for the generic version of anti-hypertension drug Diovan. Sources said the company had already filed an application with the US regulator, seeking permission for the partnership. A detailed email questionnaire sent to Ranbaxy on Monday did not elicit any response. API is the main pharmaceutical ingredient to manufacture medicine formulations. While generic drug makers are required to file Abbreviated New Drug Applications with the US Food and Drug Administration to seek approvals for formulations, they also have to submit separate drug master file, providing details of the API used in those formulations.

**Publication: The Times of India**

**Edition: Pune**

**Date: January 16, 2014**

**Headline: [Rural Woman launch silent fight against TB](#)**

**Synopsis:** The World Health Organisation (WHO) is keen on involving and engaging a wide range of

stakeholders in combating the proliferation of Tuberculosis (TB), but women in rural Maharashtra have already taken up the reins and have heralded a silent revolution in the health sector with TB treatment getting the priority. TB affected an estimated 86 lakh people and caused 13 lakh deaths globally in 2012. The casualties include 4 lakh women and 74,000 children. One third of people estimated to have TB are either not reached for diagnosis and treatment by the current health systems or are not being reported. Even in patients who are identified, TB is often diagnosed and treated late, says a WHO report. A silent revolution: As the sarpanch of Pokhari in Yavatmal district of Vidarbha, Archana Jatkar headed a revolution that aimed at checking corruption in government schemes. Jatkar ensured that all the funds allocated for treatment of TB reached the needy.

**Publication: The Hindu**

**Edition: National**

**Date: January 16, 2014**

**Headline: [Vaccine for heart attacks?](#)**

**Synopsis:** In what could be a major breakthrough in healthcare and signal relief to millions of heart disease prone people in India and the world, Apollo Hospitals said it was working with global entities on a vaccine that could prevent heart attack. "We are joining hands with doctors across the world to develop vaccines for diseases and heart disease is one among them. There were antibodies found for cancer. Clinical trials are going on for many significant breakthroughs in healthcare," group chairman Pratap C. Reddy said after the release of his biography in the city on Wednesday. Apollo Hospitals has created a healthcare ecosystem which even the Indian government could not achieve. The group's next goal would be to focus on preventive medicine, Dr. Reddy said. The hospital conglomerate will involve 3G, 4G and telemedicine technologies to take the ideas forward, he said. "Consulting, reading x-ray and other reports can be done by doctors over an iPhone. We are exploring bigger possibilities through robotics," he added. Dr. Reddy said a heart surgery, which would cost over \$100,000 in the US, could be performed in an Apollo hospital for \$2,000.

**Publication: The Hindu**

**Edition: National**

**Date: January 16, 2014**

**Journalist: R. Prasad**

**Headline: [Why oral polio vaccination must for India-bound Pakistanis](#)**

**Synopsis:** The step is being taken to safeguard India's polio-free status attained after sustained efforts. With no cases of polio being reported for three consecutive years, India will be declared as polio-free by the WHO on February 11 when random samples tested by the global health body turns out to be negative for polio. On February 24, 2012 WHO removed India from the list of countries with active, endemic, wild polio transmission. The last case of polio was reported in 2011 from West Bengal; there were 42 case of polio in 2010 and 741 in 2009. With no polio case for three years, the focus is to ensure that no cases come up in future. It therefore comes as no surprise that the government has put in place a new policy that requires every Pakistani travelling to India after January 30, 2014 to compulsorily receive oral polio vaccination "at least six weeks prior to departure to India."

**Publication: The Hindu**

**Edition: National**

**Date: January 16, 2014**

**Journalist: R. Prasad**

**Headline: [Choroideremia: gene therapy shows promise](#)**

**Synopsis:** The first Phase I clinical trial of a gene therapy for an inherited cause of progressive blindness called choroideremia — an X-linked recessive disease — has shown promising initial results. The objective of the study was to get the gene into the cells in the retina of the eye using an AAV vector without causing damage. After six months, however, the patients actually showed improvements in their vision in dim

light; two of the six patients enrolled for the study were able to read more lines on the eye chart. The authors caution that the results of the study "should not be overinterpreted." The paper is published today (January 16) in The Lancet. Robert MacLaren, the first author of the study, is from the University of Oxford. In RPE65-associated retinal degeneration, "the disease starts with loss of night vision in the first decade of life and then progresses with a gradual loss of peripheral vision and legal blindness by the fifth decade," notes the paper.

**Publication: The Hindu**

**Edition: New Delhi**

**Journalist: N. Gopal Raj**

**Date: January 16, 2014**

**Headline: [Cancer risk cut by H. pylori coevolution](#)**

**Synopsis:** When modern humans, who evolved in Africa, left their homeland some 60,000 years ago and made their way to the far corners of the world, they took along a stomach bacterium, *Helicobacter pylori*. The bacterium is today found in about half the world's population, producing inflammation of the stomach and, in some cases, stomach or peptic ulcers. But only in less than one per cent of people does the infection lead to stomach cancer, a leading cause of cancer-related deaths worldwide. Moreover, not all populations are equally susceptible to developing stomach cancer in the face of *H. pylori* infections. In Africa, for instance, infection with the bacterium is widespread but stomach cancer levels are very low, a phenomenon that has come to be called the 'African enigma.'

**Publication: The Hindu**

**Edition: National**

**Date: January 16, 2014**

**Journalist: Y. Mallikarjun**

**Headline: [Majority of Indians prone to malaria](#)**

**Synopsis:** Variations in a gene, MBL2, either protected against the disease or caused susceptibility. A majority of Indians are susceptible to malaria while certain tribal groups in the country have resistance to the disease, thanks to mutations in a single gene that determine an individual's proneness or resistivity. A new study carried out by scientists from the CSIR-Centre for Cellular and Molecular Biology (CCMB) and the Institute of Tropical Medicine, Germany, found that variations in the gene, MBL2, were responsible either for protecting against the disease or making an individual susceptible. The study done by Aditya Nath Jha et al, was published in the January 2014 issue of *Infection and Immunity*, an American journal. Pointing out that malaria was one of the major causes for morbidity and mortality in tropical and sub-tropical countries, it was noted in the study that an estimated 1.24 million deaths were caused by the disease in 2010, mostly in Africa.

**Publication: The Hindu Business Line**

**Edition: Hyderabad**

**Date: January 16, 2014**

**Headline: [Apollo working on vaccine for atherosclerosis](#)**

**Synopsis:** Apollo group of hospitals is working on a project to develop vaccine for atherosclerosis, a medical condition where patients develop plaque on the walls of arteries, adversely impacting flow of blood in arteries. "We are also involved in a project to develop an antibody for cancer cure. The research is also on to cure hypertension. The group is also working on a smaller dialysis machine," Prathap C Reddy, Chairman of Apollo group of Hospitals, said. Addressing a gathering after the release of his biography 'Healer' here on Wednesday, he related the saga of how built the group after quitting his career in the United States, following the advice of his parents.

**Publication: The Indian Express**

**Edition: New Delhi**

**Journalists: Abantika Ghosh , Surabhi**

**Date: January 16, 2014**

**Headline: [In boost to infertility treatment, govt allows import of frozen embryos](#)**

**Synopsis:** India has allowed the import of human embryos for artificial reproduction, opening up what is expected to be a huge segment of the medical tourism market. The decision will allow foreign couples to bring in frozen human embryos and rent a surrogate womb in India for the baby to be born. The relaxed rules will also apply to other infertility-related treatment such as IVF. The decision was announced through separate notifications by the Central Board of Excise and Customs and the Directorate General of Foreign Trade over the last one month. To ensure quality control, such imports will have to carry a no-objection certificate from the Indian Council of Medical Research (ICMR).

**Publication: The Indian Express (Express News Line)**

**Edition: New Delhi**

**Journalist: Pritha Chatterjee**

**Date: January 16, 2014**

**Headline: [Govt blacklists firms selected to install dialysis machines](#)**

**Synopsis:** In July last year, two firms were selected for a public-private partnership to run dialysis machines in a few government hospitals. Now, the AAP government has “debarred” the firms from participating in government tenders for a year from January 8 for their attempts to “derail the bid process, thereby causing loss to the government and harming public interest as the project has been substantially delayed and needy dialysis patients were denied the benefits due from this process”. The two companies, M/S Max Healthcare Institute Ltd and M/S Nephrocare Health Services Pvt Ltd, said they were reviewing the order and would appeal to participate in the re-tendering process since they raised legitimate concerns which had been construed as delay by the government.

**Publication: Financial Chronical**

**Edition: New Delhi**

**Journalist: B Krishna Mohan Jan**

**Date: January 16, 2014**

**Headline: [Container glass players upbeat on call for curbs on PET bottles](#)**

**Synopsis:** Glass container players are hopeful of putting their container making capacities to better use once the recommendations of Drug Technical Advisory Board (DTAB) for a ban on use of PET containers for certain pharmaceutical products come into force. At the same time, the plastic industry players feel that this will spell doom for the segment. Both these segments have seen their productions fall in Andhra Pradesh in the last two years due to power crisis. Though both of them are not planning any addition of capacities, the availability of power in the ensuing summer will determine their capacity utilisation.

**Publication: Daily News and Analysis**

**Edition: National**

**Date: January 16, 2014**

**Headline: [dna edit: A virus vanquished](#)**

**Synopsis:** India can celebrate the mammoth effort that ensured no wild polio virus case being reported for three years now. But an audit of the vaccination programme would help. On January 13, when India went three years without a single reported wild polio virus case, the day did not witness much of the chest-thumping that accompanies sporting or scientific feats. It is a stupendous achievement for a country that has borne the ignominy of being an endemic country for wild polio virus cases for long. The credit must go to a mammoth effort involving over two million volunteers who participated in immunisation and surveillance campaigns, state and central governments, UNICEF and WHO, scientists who developed the bivalent oral polio vaccine that was introduced with telling effect in 2010, and the innovative social

strategies that endeared community health workers to the masses.

**Publication: The Hindu**

**Edition: Hyderabad**

**Date: January 16, 2014**

**Headline: [Dr Reddy's in deal with US co Galena Bio for breast cancer vaccine](#)**

**Synopsis:** Pharma major Dr Reddy's Laboratories Ltd has entered into a development and commercialisation partnership with Portland-based Galena Biopharma for breast and gastric cancer drug, NeuVax (nelipepimut-S) in India. According to a release issued here on Wednesday, the Hyderabad-based Dr Reddy's would get the commercial rights for NeuVax and would lead the development of the drug. Galena would receive development and sales milestones, as well as double-digit royalties on net sales. Commenting on the partnership, G.V. Prasad, Chairman and CEO, Dr. Reddy's said: "We are delighted with our partnership with Galena Biopharma and we believe NeuVax can be a good potential treatment option to prevent the recurrence of breast and gastric cancer."

Also appeared in **The New Indian Express:** [DRL in Deal with Galena Bio for Breast Cancer Drug](#)

**Publication: The Asian Age**

**Edition: New Delhi**

**Date: January 16, 2014**

**Headline: [800 hospitals to stop cashless aid](#)**

**Synopsis:** The 800 hospitals in the country empanelled under the Central Government Health Scheme will stop cashless transactions from February 1, 2014, because, they claim, the government has not cleared arrears of `600 crore. The aggrieved hospitals have come together under the umbrella of the Association of Healthcare Providers India (AHPI) and served notice to the CGHS office in New Delhi on December 13, 2013. A meeting with the Union health secretary K.N. Desiraju held on January 9 yielded no results.