



**News Updates: December 6, 2013**

**OPPI**

**Publication:** PharmaAsia-Elsevier *(Report published further to sharing quotes with the publication)*

**Edition:** Online

**Date:** December 5, 2013

**Headline:** [India Decision Not To Limit FDI Contains Showstopper For Investors](#) *(Report not accessible on the Link. Full report pasted below for reference)*

**Synopsis:** Reports India is about to give up on limiting direct foreign direct investments in existing drug-maker operations is not necessarily welcome news to potential investors who note a discouraging proviso. Valuations of Indian pharmaceutical companies may drop with the government deciding to bar non-compete clauses in takeovers by foreign companies. This would allow sellers to re-enter the business without the usual hiatus that acquirers usually insist upon following a sale. Multinationals said they are worried by the new caveat in the foreign direct investment policy, while experts feel that this could mean 'super valuations' of domestic drug makers may become rarer. Late last week, the cabinet decided that the current FDI policy "in brownfield and greenfield projects in the pharmaceutical sector will continue subject to the additional condition that in all cases of FDI in brownfield pharma, there will not be any noncompete clause in any of the inter se agreements". The move is "worrying", said Ranjana Smetacek, director general of the Organisation of Pharma Producers of India, a grouping of foreign drug makers. "Business is a two-way street and if FDI is to be encouraged, it is important to protect the interests of both parties," she said. "Our concern is that the buying company could be in a disadvantaged situation if the seller uses its knowledge and expertise to foray into the same line of business." The grouping, however, welcomed the government's move to continue with the existing policy of allowing 100% FDI in the sector. Moves to impose stake limits in acquisitions in the rare and critical subsector and not allowing non-compete clauses were based on the concern that overseas drug makers may gain a monopoly in essential drugs and that prices may rise. The stake-limit plan was abandoned but that the proposal on the non-compete clause was accepted. Almost all big deals in the recent past including the two largest — Daiichi Sankyo's takeover of RanbaxyBSE -0.91 % and Abbott's acquisition of Piramal Healthcare's domestic formulations business — had some form of noncompete clause. The 2010 agreement to acquire Piramal Healthcare prevents promoter Ajay Piramal from entering a similar business for eight years. Deal valuations have skyrocketed in recent years. In 2008, Daiichi paid \$4.9 billion for a 63.5% stake in in all-cash deal, valuing the company at \$8.5 billion, over five times its annual sales of 2007. Two years later, Abbott acquired the Piramal unit by valuing it at nine times annual sales. This year, US firm Mylan valued Agila Specialties at \$1.6 billion, about 6.2 times annual sales. The Indian Pharma Alliance, an industry association of top domestic drug firms, declined to comment, saying it was still studying the matter. Promoters of two mid-tier local companies told ET on condition of anonymity that the move would weaken the negotiating power of Indian drugmakers and consequently the premiums they demand.

**Publication:** Afaqs!

**Edition:** Online

**Date:** December 6, 2013

**Headline:** [Healthcare Brand Summit: Adapting to contemporary communication channels](#)

**Synopsis:** Day 1 of Healthcare Brand Summit had many of the speakers professing the importance of building strong, relatable brands in healthcare and pharmaceutical industries and how the companies need to look beyond the conventional marketing techniques and tools. Organised by afaqs!, the two-day summit, which is the first of its kind, was held at Hilton Hotel, Mumbai, and was supported by OPPI and Brands of Desire. DDB Remedy is the knowledge partner. Ranjit Shahani, country president, Novartis India, and former OPPI president, kick-started the session by introducing the concept of a powerful brand. He said a brand could be a valuable asset for a company to increase its shareholder value. However, the healthcare industry has been a very poor investor in branding and a lot of work was needed on this. Shahani's keynote address was followed by a panel discussion on 'The critical value of brands in a changing Indian healthcare industry'. Moderated by DDB Remedy president Soumitra Sen, the

panel comprised Kewal Handa, managing director, Salus Lifecare, and former MD, Pfizer; Swati Dalal, director, marketing excellence, Abbott Healthcare Solutions; and Sharad Tyagi, managing director, Boehringer Ingelheim India. Lawrence Ganti, country director, Merck Serono, shared the various social media initiatives the company was taking. He highlighted that in his company, expenditure on traditional marketing had dropped by 60 per cent. Instead, the company now employed a multi-channel marketing approach, where it used social media, telemarketing, web portals and domains and mobile vans to disseminate information and engage with the target audience.

## FDI

**Publication:** Business Standard (Reproduced from [IANS](#))

**Edition:** National

**Date:** December 5, 2013

**Headline:** [US trade body welcomes Indian move on FDI in pharma](#)

**Synopsis:** The US-India Business Council (USIBC) has welcomed the Indian government's decision to reject a proposal limiting pharmaceutical investment caps to 49 percent in the brownfield investment sector. "Such a reversal would have sent chilling signals to investors, chased capital to other markets, and prevented domestic companies from growing and collaborating," the trade advocacy group comprising over 350 top-tier US and Indian companies said Wednesday. "Instead, the decision by the Government of India reassures investors that India is not going back on reforms," the group said. The announcement will encourage competition and investment in the pharmaceutical sector which will continue to create jobs and ensure that patients receive access to important medicines, it said.

**Publication:** Manoramaonline

**Edition:** Online

**Date:** December 4, 2013

**Headline:** [Spanners and cogged wheels](#)

**Synopsis:** When Sharma proposed a cap of 49 per cent foreign equity for the pharmaceutical sector, both Chidambaram and Sibal asked how could the commerce minister deny majority ownership rights, when he was ready to concede management rights to the foreign investor. They said the Prime Minister Manmohan Singh had mandated that foreign direct investment should be allowed in the pharma sector, and why was the Commerce Minister not going by the spirit of the Prime Minister's direction. Both wanted their ministries to be consulted on the issue. When the economy was under great pressure six months ago, Chidambaram had constituted a committee under economic affairs secretary Arvind Mayaram to suggest ways of increasing Foreign Direct Investment to help the distressed rupee. Manmohan Singh who had handled finance in 1990s, and had also worked in the Commerce Ministry as a bureaucrat agreed with Chidambaram and Sibal.

## Patents / Intellectual Property Rights / Compulsory Drug Licensing

**Publication:** The Economic Times (Reproduced from AFP)

**Edition:** National

**Date:** December 5, 2013

**Headline:** [Strides Arcolab may not get \\$250 million from Mylan for Agila deal](#)

**Synopsis:** US generic drug specialist Mylan said Thursday it had completed its \$1.75 billion acquisition of a unit of India's Strides Arcolab, boosting its presence in the high-growth injectable drugs market. The Pennsylvania-based Mylan confirmed the buyout of Agila Specialities, which makes injectables, with some restructuring of the deal since it was first announced in February. The deal now includes a "hold back" provision of \$250 million of the total price, to be paid to Strides only if it fulfils some regulatory conditions. The global generic injectable drugs market is expected to grow at an annual rate of 13 percent between 2011 and 2017, driven by patent expiries and outpacing most other dosage forms, the US firm said.

**Publication:** Business Standard

**Edition:** National

**Date: December 5, 2013**

**Journalist: Ujjval Jauhari & Ram Prasad Sahu**

**Headline: [Strong pill in medium doses](#)**

**Synopsis:** Large-cap pharma companies have been major outperformers in the past few years, trumping the broader markets and smaller peers. Year-to-date, large-cap pharma stocks have outperformed. The valuation discount between the two categories existed earlier, too, given robust product pipelines, high earnings visibility, strong balance sheets and healthy return ratios. Having resolved Food and Drug Administration (FDA) related issues, the company is on a strong wicket in the US after the re-launch of cephalosporin class of drugs from Unit-VI (one of the affected facilities) and market share gains by products launched in 12 months. The increase in injectibles at Unit IV and at least three injectibles launches in 30 days (all in the shortage list of FDA, with a market size of \$68-80 million) bolsters its prospects. Analysts at Edelweiss say sustainable operational performance will restore confidence over execution, resulting in valuation re-rating. Notably, Aurobindo has the largest pipeline in the US. While the domestic pharma (14 per cent of revenues) is growing at 30 per cent annually and listing of its Syngene could unlock value, the bigger trigger is the opening of the regulated markets to its biosimilars after the expiry of patents of key drugs in CY15.

**Publication: The Telegraph - India**

**Edition: Online**

**Date: December 5, 2013**

**Headline: [Tech innovation left in govt hands](#)**

**Synopsis:** Government laboratories and academic institutions remain the drivers of innovation in India despite decades of efforts by scientific agencies to coax Indian industries to invest in research and development, says a new report released today. The state of innovation report has been released by the intellectual property and science business division of Thomson Reuters, a global information services company. It has shown that more innovation happens in India's pharmaceuticals sector than in any other, but much of it is incremental — new methods of making known drugs. India has long been viewed as under-investing in innovation relative to other global economies. An analysis last year by the World Bank and other institutions had ranked India seventh in research and development. Among an estimated 40,000 patent applications filed in India last year, about 8,000 originated in India, meaning the innovation underlying those applications had been done in India. Thomson Reuters' analysts focused on about 6,000 of the Indian-origin patent applications.

**Publication: The People's Chronicle**

**Edition: National**

**Author: Arindham Chaudhuri, Management Guru and Hony Director of IIPM Think tank**

**Date: December 5, 2013**

**Headline: [Time to kill the foreign pill!](#)**

**Synopsis:** Back in 2003, George Washington University started the GWU India Project, a project that gave dramatic insights into how the 'business' of lobbying works to a nation's detriment. Private companies and associations were found to be the funding entities for R&D and consulting; and in turn, these entities got public policy and judicial decisions fabricated and influenced to their benefit with respect to Intellectual Property (IP). Foreign Pharma has always kept a close eye on Indian pharmaceutical manufacturers and related drug legislations, especially as most of our manufacturers are infamous for producing low cost generic unbranded drugs, whose branded versions are being sold at prices that are phenomenally high and out of reach of those millions of Indians who are waiting for lifesaving drugs and struggling with treatable diseases. Consequently, US pharma giants have been continually lobbying politically with their government to pressurise the Indian government to insert a cap on permits that are issued to domestic companies for making low-cost copies of patented drugs. Even companies like Pfizer and Merck met the Department of Industrial Policy & Promotion (DIPP) to lobby against compulsory licenses being issued by India. For the uninitiated, a compulsory licence is a permission issued to any local manufacturer allowing him to produce the so-called 'copied versions' of patented medicines without any prior permission of the original patent owner.

**Publication: Mint**

**Edition: National**

**Date: December 5 2013**

**Headline: [Jubilant Life Sciences shares fall after FDA warning](#)**

**Synopsis:** The drugmaker had received a warning from the US Food and Drug Administration over manufacturing practices at one of its US facilities, sending its shares the limit-down 10%

**Publication: The Times of India**

**Edition: National**

**Date: December 5, 2013**

**Headline: [Regulatory nod for biosimilar, affordable drug for breast cancer](#)**

**Synopsis:** Biocon Ltd, a biotechnology company, recently received marketing authorization from the Drugs Controller General of India (DCGI) for biosimilar Trastuzumab for the treatment of Her 2+ metastatic breast cancer. The company claimed it to be the world's first biosimilar version of Herceptin to be brought to the market. The biosimilar Trastuzumab, being developed jointly with Mylan, will be marketed in India under the brand name of CANMAb. It is expected to be available to Indian patients in Q4 FY14.

**Publication: The Times of India**

**Edition: National**

**Date: December 5, 2013**

**Headline: [Affordable drug for small cell lung cancer](#)**

**Synopsis:** Cadila Pharmaceuticals recently launched Mycidac-C, touted as an affordable, unique and innovative drug for the treatment of lung cancer. It is an innovative research product for patients suffering from non small cell lung cancer (NSCLC). The Drug Controller General of India (DCGI) has approved for the launch of the drug in India.

**Publication: The Times of India**

**Edition: Online**

**Date: December 5, 2013**

**Headline: [FDA teams raid drug stores, detect unlicensed premises](#)**

**Synopsis:** In a major crackdown in Gurgaon, a team of the Food and Drugs Administration department Haryana on Thursday swooped down on four chemist shops and one unlicensed premises in the South City 1 Arcade and Silokhra village. The Food and Drugs Administration department Haryana acted on a tip-off and formed five teams, which simultaneously raided the Shree Ram Medical Agency, S R Pharmacy, Laxmi and Gurukripa Chemist Shops.

**Publication: The Times of India**

**Edition: National**

**Date: December 6, 2013**

**Headline: [Poor awareness of implants, FDA chief suggests roping in NGOs to educate patients](#)**

**Synopsis:** Three years after Johnson & Johnson recalled its all metal hip implant globally, less than 10% of the 4,500 Indian patients have approached the company's redressal agency. The Indian response, among other things, highlights how most patients continue to know little about implantation procedures or its implications. Food and Drug Administration commissioner Mahesh Zagade suggested that NGOs should step in to educate patients. "We also need specialized courts and compensation laws in the country to tackle these emerging issues better."

**Publication: The Times of India**

**Edition: National**

**Date: December 6, 2013**

**Headline: [Chemists allege harassment, call for bandh from Dec 16](#)**

**Synopsis:** The Maharashtra State Chemists' and Druggists' Association has called for a three-day bandh in the state from December 16 to protest against alleged harassment by government officials, said the office-bearers of the association on Thursday. Government officials have been acting tough against chemists operating without a qualified pharmacist. "We want every medical store to have qualified pharmacists. But there should be some leniency or considerate approach if the pharmacist has gone on leave or has taken a break for a few hours for some personal work. Officials do not consider such conditions while initiating action against the shops," said an officer-bearer of the association.

**Publication: The Hindu Business Line**

**Edition: National**

**Date: December 5, 2013**

**Headline: [Indian Bank, Apollo Hospitals roll out health card](#)**

**Synopsis:** Indian Bank and Apollo Hospitals have launched a health card that will enable select customers of the bank get a discount on the hospital's services and products. Customers can get up to 20 per cent discount from the Apollo Hospitals chain for a range of services, including room charges, medical check up, investigation fees and pharma products. T. M. Bhasin, Chairman and Managing Director, Indian Bank, said this is a gesture from Apollo Hospitals to mark its long-standing association with the bank. Indian Bank, in turn, will use this card to reward its customers.

**Publication: The Hindu**

**Edition: National**

**Date: December 5, 2013**

**Headline: [USFDA warns Jubilant Life](#)**

**Synopsis:** Jubilant Life Sciences Ltd (JLL), on Thursday, said it had received a warning letter from the US Food and Drug Administration (USFDA) over violation of manufacturing norms at one of its plants located in Washington state. In a statement, the company said one of its manufacturing facilities, Jubilant HollisterStier, LLC (JHS), located at Spokane, Washington state, U.S., has been issued a warning letter by the USFDA.

**Publication: Pharmabiz**

**Edition: Online**

**Date: December 5, 2013**

**Headline: [Researchers develop advanced 'PharmaCheck' technology to check substandard drugs](#)**

**Synopsis:** Researchers at Boston University (BU) in collaboration with U S Pharmacopoeial Convention's (USP) Promoting quality Medicines (PQM) programme have developed 'PharmCheck' an advanced inexpensive and portable device to detect poor quality medicines across the world. Initially, PharmaCheck quality screening technology is developed by Recognized Among "World Changing Ideas of 2013". This new tool is scheduled for field testing in early 2014 in sub-Saharan Africa, a region heavily threatened by poor quality medicines. Since 2009, USP has been providing technical assistance to regulatory, quality control and health care personnel in developing countries via PQM as a central strategy in the fight against substandard and counterfeit medicines.

**Publication: Pharmabiz**

**Edition: National**

**Date: December 6, 2013**

**Headline: [Govt to take action against violators based on their explanation and reports: Pondicherry health secretary](#)**

**Synopsis:** The Pondicherry health secretary has stated that the state government will initiate action against the

erring pharma companies based on the reports and explanations submitted by these manufacturing units for the show-cause notices issued by the health department recently. State health secretary G Ragesh Chandra said that he was not in the office for the last one week, but the files will be looked into shortly. The government in the Union Territory had given show-cause notices to more than 20 pharmaceutical manufacturing companies last month finding violation of provision of 122E of the Drugs and Cosmetics Rules. There was allegation that certain companies had engaged in manufacturing of FDC products without getting approval of the drugs controller general of India (DCGI). For the production of these combination drugs they got licence from the state licensing authority. It was further alleged that the action of the SLA was not binding on the Rules of the national regulator.

### Drug Pricing

**Publication:** Mint

**Edition:** National

**Date:** December 5, 2013

**Headline:** [Cipla acquires Croatian distributor Celeris](#)

**Synopsis:** Cipla acquires its distributor for an undisclosed sum as part of a larger plan to build direct presence in global markets. Cipla Ltd, India's second largest drug maker by market share, said on Thursday that it had acquired its distributor in Croatia—Celeris d.o.o—for an undisclosed sum as part of a larger plan to build a direct presence in global markets. Cipla acquired 100% equity in Cipla Medpro South Africa Ltd in South Africa earlier this year and bought a majority stake in UCIL, Uganda, in November. Cipla, which transformed the global HIV-AIDS treatment scenario by offering its generic anti-retroviral combination drug at up to one-fortieth the price charged by multinational drug makers in the developing world, wants to leverage its global reputation as a trusted generic drugmaker to strengthen its global presence.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** December 6, 2013

**Headline:** [NPPA fixes prices of 18 more formulations](#)

**Synopsis:** As part of the ongoing process of revising the prices of essential medicines in line with the new Drug Price Control Order (DPCO), the National Pharmaceutical Pricing Authority (NPPA) has fixed the prices of 18 more formulation packs. The price regulator has already fixed the prices of over 350 formulations so far, before the present batch of 18 packs. Besides, it had also found no information about 154 formulations, leaving the agency with no options to fix prices. Thus over 500 formulations have been covered.

### Clinical Trials

**Publication:** Business Standard

**Edition:** National

**Date:** December 5, 2013

**Headline:** [Kiran Mazumdar Shaw, the city crusader](#)

**Synopsis:** Shaw has always been very vocal about issues relating to her industry, and has long been an advocate for cheap generics, whether at industry conclaves or through opinion pieces in newspapers. When Ranbaxy was slapped with a \$500-million penalty by the US department of justice for falsifying data and other violations, Shaw wrote that the incident should be a wake-up call for the Indian pharmaceutical industry to safeguard their reputation through "action rather than rhetoric". She is also vocal about other issues relating to the biotech and pharmaceutical industries, such as speaking out against the curb on clinical trials.

**Publication:** SiliconIndia

**Edition:** Online

**Date:** December 5, 2013

**Headline:** [SAP Recognized By White House For Enabling Real-Time Personalized Medicine](#)

**Synopsis:** At a recent event sponsored by the White House, the National Science Foundation and the Networking

and Information Technology R&D program, SAP AG was recognized for its collaborative efforts to enable real-time personalized medicine through innovation with Stanford University and the National Center for Tumor Diseases Germany. The Washington, DC-based event, Data to Knowledge to Action, featured public and private organizations that enhance scientific discovery and biomedical research and derive greater value for consumers by innovating Big Data tools and technologies. Outside the U.S., SAP is collaborating with the National Center for Tumor Diseases in Heidelberg, Germany, to pilot analysis and collaboration tools based on SAP HANA. These tools are designed to enable physicians and researchers to securely analyze clinical and genomic data in real time to help dramatically improve cancer diagnostics, identify personalized treatment options and facilitate matching patients with the best clinical trials.

### General Industry

**Publication:** The Times of India

**Edition:** National

**Date:** December 6, 2013

**Headline:** [Mylan sees India as a global hub](#)

**Synopsis:** Mylan, the world's third-largest generic and speciality pharmaceutical company, has invested in excess of \$3 billion in the last six years — roughly 50% of its revenues last year — to build itself into a big player in India's pharmaceutical market. The US-based company, which has strung together multiple billion-dollar acquisitions in the country, is perhaps among the top three pharmaceutical companies in India with a workforce topping 12,000 people. In fact, Mylan's India operations account for half of its global workforce and is double its US headcount.

**Publication:** The Times of India

**Edition:** National

**Date:** December 6, 2013

**Headline:** [Actis may sell Sterling Hospitals back to founder](#)

**Synopsis:** Private equity (PE) major Actis Capital is considering a sale of Ahmedabad-based Sterling Hospitals back to its founder Girish Patel and his family — also the erstwhile promoters of Paras Pharma — after a top bidder for the hospital chain lowered its acquisition price, multiple sources privy to the matter said. Azim Premji and Temasek-backed HealthCare Global (HCG) had bid over Rs 450 crore after Sterling's controlling shareholder Actis mandated Kotak Investment Banking to sell the company. However, ten days back, the Bangalore-based cancer care specialist dropped its offer price to Rs 325 crore, citing profitability concerns post a due diligence process, sources cited earlier told TOI.

### Innovation

**Publication:**

**Edition:** National

**Date:** December 5, 2013

**Headline:** [US healthcare IT company Allscripts expands in India](#)

**Synopsis:** Allscripts India, a subsidiary of NASDAQ-listed healthcare information technology (IT) provider Allscripts Healthcare Solutions Inc, has opened a new and expanded office in Vadodara as part of the company's expansion plan in research, development, innovation and global growth. According to a press statement issued from Allscripts Vadodara office, it says that the new office, consisting of two floors located at the center of Vadodara, will initially house more than 275 existing Allscripts team members. With approximately 30,000 square feet in available space, the office will have the capacity to expand and accommodate up to 400 employees. The company makes IT solutions that connect healthcare fraternity like physicians, hospitals and post-acute organizations.

### Access and Affordability

**Publication:** Business Standard

**Edition:** National

**Date:** December 5, 2013

**Headline:** [Petition seeks improved access to pain relief drugs](#)

**Synopsis:** Human Rights Watch and Pallium India Thursday wrote a petition to Prime Minister Manmohan Singh, seeking improved availability of pain relief medicines, and to press parliament to approve changes to the Narcotic Drugs and Psychotropic Substances (NDPS) Act. The act makes stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances. The petition said the amendment bill, which would still include the restrictions to prevent abuse of medicines like morphine, intends to ensure its easy availability to patients suffering from unbearable pain. "The passage of the NDPS Amendment Bill will lead to improved access to pain relief medicines and help ease the suffering of millions of patients and their families in India, thereby improving their quality of life," it said.