



**News Updates: December 16, 2013**

### Drug Pricing

**Publication:** The Financial Chronicle (*Reproduced from PTI*) (also appeared in Business Standard, The Pioneer and Deccan Herald)

**Edition:** National

**Date:** December 16, 2013

**Headline:** [US generic drug fee plan may benefit Indian firms](#)

**Synopsis:** The US Food and Drug Administration (FDA) could consider bringing some relief in payment of fees to small generic drugmakers, including those from India, if a newly proposed legislation is enacted. With the US FDA proposing to raise the fees for generic drug makers for the next financial year, concerns had been raised on the financial burden that the one-size-fits-all fee structure creates for the smaller units, which typically face cash-crunch problems. Congressman Robert Hurt introduced a legislation along with Congressman Phil Roe this month, seeking to level the playing field for generic drug user fees so that smaller manufacturers would be expected to pay fees that reflect the relative size of their firms compared to the giants. The Small Manufacturer Protection Act of 2013 would add new provisions allowing for waivers and refunds of user fees. "The expectation that all manufacturers would pay the same fees, regardless of size, is unrealistic and should be adjusted to accommodate smaller companies so they can continue to innovate, produce and compete," Hurt said.

### FDI / Foreign Investment in Pharma / M&As in Pharma

**Publication:** Mint

**Edition:** National

**Journalist:** Ravi Ananthanarayanan

**Date:** December 16, 2013

**Headline:** [Torrent gets prized parts of Elder's portfolio at a good price](#)

**Synopsis:** Torrent Pharmaceuticals Ltd's acquisition of Elder Pharmaceuticals Ltd's domestic formulations business (including Nepal) will please those in the government who look at foreign direct investment (FDI) in healthcare with suspicion. An Indian pharmaceutical business is sold but the ownership remains in Indian hands. Whether that played any role in the transaction is not known, but this transaction is likely to be completed sooner, compared with one that required the foreign investment promotion board's (FIPB's) approval. That should suit Elder as it needs money to repay its debts. The company has been facing cash flow problems and on 7 November said in a stock exchange announcement that it had defaulted on a Rs.10 crore interest payment to debenture holders.

**Publication:** The Financial Chronicle (*Reproduced from Bloomberg*)

**Edition:** National

**Journalist:** Jodi Xu

**Date:** December 16, 2013

**Headline:** [J&J said to get 3 bids of \\$4b each](#)

**Synopsis:** The offers were for its Ortho Clinical business and includes a joint offer from the Blackstone group, Carlyle group and Danaher.

**Publication:** The Business Standard

**Edition:** National

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

**Date:** December 16, 2013

**Headline:** [Street concerns at Torrent-Elder deal](#)

**Synopsis:** Torrent Pharma's acquisition of Elder Pharma's branded domestic formulation businesses in India and Nepal has not gone down well with the Street.

Though the brands would enhance Torrent's portfolio, increasing debt and its ability to scale up the business are key parameters the Street will keep an eye on. The Rs 2,000-crore deal will increase Torrent's current debt of Rs 913 crore and the debt to equity ratio to 0.4 as of September. The company's plans to fund the acquisition through a mix of internal accrual (it has cash of Rs 800 crore) and debt. This, coupled with lower margins for Elder's product portfolio and higher employee costs, could pull down the profitability of Torrent. While it has overall margins of 22-23 per cent, those of Elder at the operating level are around 16 per cent. Given these concerns, Torrent fell 4.1 per cent to close at Rs 479 on Friday; Elder's loss was eight per cent, to Rs 298.30.

Analysts are divided on the deal valuations.

**Publication:** The Telegraph (Reproduced from PTI)

**Edition:** Online

**Date:** December 15, 2013

**Headline:** [Private equity deals soar](#)

**Synopsis:** Indian companies signed 393 private equity (PE) deals totalling \$9.67 billion in the January-November period of this year, registering an increase of 36.38 per cent over the corresponding period a year ago, says a report. KKR's investment of \$200 million in Gland Pharma Ltd was termed as the deal of the month.

#### FDA

**Publication:** Pharmabiz

**Edition:** Online

**Journalist:** Ramesh Shanker

**Date:** December 16, 2013

**Headline:** [Experts for making pharmacovigilance mandatory in CDA Bill](#)

**Synopsis:** Experts in the industry have recommended to the parliamentary standing committee on health and family welfare that examines the Central Drugs Administration (CDA) Bill to make pharmacovigilance mandatory in the proposed CDA Bill for continuous monitoring of adverse drug reactions (ADRs). Presently, the parliamentary standing committee headed by Brajesh Pathak is examining the Drugs and Cosmetics (Amendment) Bill, 2013 that seeks to establish the CDA. The bill seeks to centralise licensing in 17 categories of very critical drugs included in the proposed Third Schedule of the Act.

#### Company News

**Publication:** Reuters India (Also in The Economic Times, The Hindu Business Line and Business Standard online)

**Edition:** Online

**Date:** December 16, 2013

**Headline:** [GSK to spend \\$1 billion to raise stake in Indian unit](#)

**Synopsis:** GlaxoSmithKline Plc (GSK)(GSK.L) said on Monday it plans to raise its stake in its Indian pharmaceutical unit to up to 75 percent from 50.7 percent through an open offer in a deal worth about 629 million pounds. With the latest India deal, GSK is set to spend close to \$2 billion in roughly a year to increase its holdings in two listed Indian companies, underscoring the British drugmaker's drive to deepen its footprint in emerging markets.

**Publication:** Business Standard

**Edition:** Online

**Date:** December 16, 2013

**Headline:** [Aurobindo Pharma extends gain on USFDA nod for anti-depressant drug](#)

**Synopsis:** Aurobindo Pharma is trading higher by 2.4% at Rs 317, extending its Friday's 4% rally, after said it has received the final approval from the U.S. health regulator to manufacture and market Duloxetine Hydrochloride Delayed-Release capsules, an anti-depressant drug, in the American market. "The market size of the product is estimated to be \$5.4 billion for the twelve months ending September 2013," Aurobindo Pharma said in a regulatory

filing. The company has a total of 188 Abbreviated New Drug Application (ANDA) approvals from USFDA, of which 163 are final approvals and 25 are tentative approvals, it added.

## General Industry

**Publication: The Times of India**

**Edition: National**

**Journalist: Shobhita Dhar**

**Date: December 16, 2013**

**Headline: [Testosterone deficiency may be striking early](#)**

**Synopsis:** Women aren't the only ones at the mercy of hormonal fluctuations. Now men, in the age group of early 30s and 40s, are grumpy, tired, sleepless and lacking libido because of low levels of testosterone — the male hormone. Though no official statistics are available, many endocrinologists are reporting an increasing incidence among younger men. Dipping testosterone threw Vipul Khanna's work and family life out of gear two years ago. "I had problems like tiredness, insomnia and low libido. I even had difficulty in concentrating and remembering things," says Khanna, now 38. Diagnostic tests revealed that his testosterone level had plunged down to below 200; normal range is 400-450. "Immediately, he was put on testosterone shots, to be taken once in 21 days in addition to a B12 supplement, as he was also deficient in this vitamin," says Dr Deepak Chaturvedi, his endocrinologist based in Mumbai. Gradually, his levels became normal.

**Publication: Pharmabiz**

**Edition: Online**

**Journalist: Joseph Alexander**

**Date: December 16, 2013**

**Headline: [IPC to debate unbridled approvals given to new pharmacy colleges](#)**

**Synopsis:** The forthcoming Indian Pharmaceutical Congress (IPC), the largest gathering of stakeholders, will deliberate among many things the unbridled approval accorded to new pharmacy colleges without taking into consideration of the demand side and thus causing a spurt in unemployment in the market. The 65th edition of IPC, scheduled at Amity University, Noida near here from December 20-22, is also expected to come up with a strong resolution on the need for taking up an assessment by the Government on the market conditions, though new opportunities were thrown open for the pharmacists.

**Publication: The Hindu**

**Edition: Noida/Delhi**

**Date: December 16, 2013**

**Headline: [Cancer survivors come together](#)**

**Synopsis:** With the aim to raise awareness about curability and preventive measures in successfully combating breast cancer, the India Rajiv Gandhi Cancer Institute and Research Centre, (RGCI) Delhi, organised "The pink ribbon meet – annual symposium for breast cancer survivors" on Saturday. Breast cancer survivors and those working in the area of breast cancer experts participated in the event. RGCI senior consultant and head of breast, thoracic and soft tissue services Dr. Kapil Kumar said: "In India around 60 per cent of breast cancer patients are in an advanced stage when they go for treatment. Creating awareness about causes, issues and challenges in preventing and surviving breast cancer and latest treatments is the key agenda of this meet."

**Publication: The Hindu (also appeared in The Tribune)**

**Edition: Noida/Delhi**

**Date: December 16, 2013**

**Headline: [Free medical support for poor diabetic children](#) (online headline- Delhi: Free insulin for poor children)**

**Synopsis:** Many diabetic children from the economically weaker sections of the society in the national capital will be provided insulin free of cost, said a Delhi based diabetic centre on Sunday. Delhi Diabetic Research Center (DDRC)

will provide insulin free of cost to 150 poor children suffering from Type 1 diabetics. The initiative was announced by DDRC at a day-long event at Talkatora Stadium in New Delhi. "Children with Type 1 diabetes need daily dose of insulin, regular monitoring of glucose level, periodic visits to the doctors and subsequent pathology tests, which becomes a bit unaffordable for the weaker section of the society," said Ashok Jhingan, diabetologist and chairman, DDRC. All the children provided free insulin are between the age group of 0-18. "Initially we will provide free insulin to 150 children and slowly shall extend the reach to more children," Jhingan added.

**Publication: The Financial Chronicle**

**Edition: National**

**Journalist: Falaknaaz Syed**

**Date: December 16, 2013**

**Headline: [Group health cover cost may decline on rise in competition](#)**

**Synopsis:** Companies who are going to renew their insurance policies on January 1 may get discounts on group mediclaim policies, but are likely to see their premiums remain unchanged in case of property insurance policies. A significant number of companies including most multinationals renew their insurance policies on January 1. They buy group health insurance cover for their employees besides fire (read property) insurance policy, industrial all-risk policy, business interruption policy to protect their offices, buildings, power plants, refineries against fire and act of God perils/catastrophes such as earthquake, storm, rain, flood and thunder. Heads of insurance companies and insurance brokers told Financial Chronicle that despite group health insurance being a loss-making business, competition among general insurers is resulting in reduction in premiums rates. However, rates would remain stable for property covers.

**Publication: The New Indian Express**

**Edition: Online**

**Journalist: Papiya Bhattacharya**

**Date: December 16, 2013**

**Headline: [Still a Long Way to Go for HIV Vaccine](#)**

**Synopsis:** Reports about a series of clinical trials called the STEP trials, to test the efficacy of a HIV vaccine, have revealed that people injected with the vaccine had a higher possibility of getting infected. These trials involved 3,000 uninfected people in North and South America, Australia and Phambili in South Africa. Dr Rajat Goyal, Country Director of International AIDS Vaccine Initiative (IAVI) told Express, "In the STEP Phambili and HVTN505 studies, perhaps the vaccine was not able to prevent infection. Currently available data does not provide evidence beyond Ad5 (adenovirus-5) when considering safety issues with adenovirus vectors at large. The data for Ad5 used in the STEP/Phambili and HVTN505 trials cannot be generalised for other adenoviruses." Referring to IAVI's current work, he said India is an important player in its plans.

**Publication: Ummid.com (Reproduced from IANS)**

**Edition: Online**

**Date: December 15, 2013**

**Headline: [Mumbai pharma summit to honour excellence, promote ethics](#)**

**Synopsis:** The stage is set for the 6th summit among doctors, drug makers and regulators here later this month that will not only discuss issues concerning the \$17-billion Indian pharma industry but also honour top doctors and firms in 40 categories. Organised by Network 7 Media Group's Pharmaleaders, an analytical healthcare media in Asia, the 6th Annual Pharmaceutical Leadership Summit Dec 27 will provide a platform for greater interaction among Indian medical practitioners and drug makers. Some other issues up for discussion include foreign investment policy, clinical trial approvals, compulsive licensing, slowdown in the launch of new drugs, regulation and the lowering of 348 drugs this year under the price control regime.

## Innovation

**Publication: Mint (Interview)**

**Edition: National**

**Journalist: C.H. Unnikrishnan & Unnikrishnan S.**

**Date: December 16, 2013**

**Headline: ["India is an invest-to-win market for us"](#)**

**Synopsis:** In October, Merck and Co. Inc., the world's fourth largest drug maker, announced a restructuring of its global operations to sharpen its commercial and research focus. Under the new plan, the US firm will focus on diabetes management, cancer therapies, vaccines and critical care business segments. The company also plans to cut about 20% of its 81,000 worldwide workforce and sell of some of its real estate assets to improve its performance in the short term and save \$2.5 billion in costs by 2015.

While it has picked up 10 priority markets—the US, Japan, France, Germany, Canada, UK, China, Brazil, Russia and Korea—which account for the majority of the company's revenue, the group will keep investing in newer markets such as India for long-term value creation, according to Merck's emerging markets president Kevin Ali, who heads a business region that includes some 116 countries. India will make a bigger contribution as it is going to be an innovation factory for the US multinational (also known as MSD Pharma outside the US and Canada), Ali said in an interview during his visit to India earlier this month.

**Publication: Pharmabiz**

**Edition: Online**

**Date: December 16, 2013**

**Headline: [AstraZeneca phase III study of lesinurad in gout patients meets primary endpoint](#)**

**Synopsis:** AstraZeneca, a global, innovation-driven biopharmaceutical business, has reported top-line results from LIGHT, a phase III study investigating the potential of lesinurad as a monotherapy in the small population of gout patients who are intolerant to, or otherwise cannot take, one or both xanthine oxidase inhibitors allopurinol and febuxostat. Lesinurad is an investigational agent being studied as a selective uric acid re-absorption inhibitor (SURI) that inhibits the URAT1 transporter, normalising uric acid excretion and reducing serum uric acid (sUA).