

**Clinical Trials****Publication: The Times of India****Edition: Mumbai** (*appeared online on December 17, 2013*)**Date: December 19, 2013****Headline: ['Bhopal gas victims used as guinea pigs for drug trials'](#)**

**Synopsis:** Pharmaceutical companies Quintiles and Sanofi have failed to follow norms while conducting clinical trials of their new drugs on Bhopal gas leak survivors, the health ministry informed the Supreme Court. During hearings on alleged flouting of norms by pharmaceutical majors in conducting clinical trials on humans, the court had ordered the health ministry not to proceed with the clinical trials of 157 new drugs/formulations till a stricter regime was put in place.

**Publication: Reuters****Edition: Online****Date: December 19, 2013****Headline: [Gilead to seek okay for combo hepatitis C pill in Q1](#)**

**Synopsis:** Gilead Sciences Inc, based on favorable new clinical trial data, said it will seek U.S. approval in the first quarter of 2014 for a once-daily tablet containing two new treatments for hepatitis C. The company previously had said it would seek marketing approval in the first half of next year for the combination tablet, which would pair Gilead's recently approved Sovaldi (sofosbuvir) and its experimental drug ledipasvir.

**Publication: Pharmabiz****Edition: Online****Date: December 19, 2013****Headline: [EMA to push ahead in 2014 towards publication and access to clinical trial data](#)**

**Synopsis:** The European Medicines Agency (EMA) has now reviewed all comments received on its draft policy on publication and access to clinical trial data. While the comments received showed that there is large support for the Agency's plans to allow access to clinical trial data submitted as part of marketing authorisation applications, they also highlighted that there is a need for further analysis and clarification of certain aspects.

**Publication: The Financial Express****Edition: National** (*Opinion*)**Date: December 19, 2013****Headline: [Good Medicine](#)**

**Synopsis:** Much like oil companies, Big Pharma has been a reliable movie villain in a post-Cold War world, with its shadowy and secretive practices also providing fodder to conspiracy theorists worldwide. That pharmaceutical companies have a major public relations problem on their hands is no secret, given the frequency with which headlines about faked drug trials, untested medicine, patent lawsuits and unadvertised side-effects show up. So, for one of the world's largest drug manufacturers—GlaxoSmithKline—to voluntarily usher in an overhaul of its drug promotion methods is a much-needed, and unexpected, demonstration of ethical business conduct in an industry where perception of such is sorely lacking.

**Edition:** National

**Date:** December 19, 2013

**Headline:** [Panel Opposes structures of new drug regulator](#)

**Synopsis:** Parliament's Standing Committee on Health opposed the structure of the new drug regulator proposed by the government under the Drug and Cosmetic Bill, calling it 'unprecedented' and 'not acceptable' as no other regulatory body in or outside the country had such a composition. The health ministry introduced the Drugs and Cosmetics Bill in this year's monsoon session of Parliament. It recommended the creation of a Central Drugs Authority (CDA), a 19-member panel, headed by health secretary to regulate drugs, cosmetics, medical devices and clinical trials in the country.

**Publication:** The Economic Times

**Edition:** National (*Reproduced from PTI*)

**Date:** December 19, 2013

**Headline:** [Parliamentary panel calls for creation of Central Drugs Administration for stronger tabs](#)

**Synopsis:** A Parliamentary panel has recommended creation of a professionally-managed Central Drugs Administration to check malpractices in drug manufacturing after rejecting the proposal for the setting up of a Central Drugs Authority under the amended Drugs and Cosmetics Act. In its report on the Drugs and Cosmetics (Amendment) Bill, 2013, the Parliamentary Standing Committee on Health has said that there is a need for effective discharge of enforcement activities which requires a strong, professionally-managed administration which can take action against unscrupulous manufacturing companies.

**Publication:** The Financial Express

**Edition:** New Delhi

**Journalist:** Jayati Ghose

**Date:** December 19, 2013

**Headline:** [Pharma cos seek govt help to end trade margin row](#)

**Synopsis:** Domestic pharmaceutical players have sought government intervention to resolve the trade margin issue with distributors who are refusing to stock essential medicines of specific companies till their demands of higher commissions are met. While companies such as Abbott and Sun Pharma, who have not yet agreed to raise trade margins, are facing a boycott of their price-controlled drugs by stockists, others like Cipla, Torrent, Mankind and Lupin have succumbed under pressure and eased margins for retailers and distributors to ensure continued availability of their drugs.

**Publication:** Hindustan Times

**Edition:** Mumbai

**Date:** December 19, 2013

**Headline:** ['Will not pay doctors to promote us'](#)

**Synopsis:** After pharmaceutical giant, GlaxoSmithKline Pharmaceutical Ltd (GSK) in a landmark announcement on Monday said that it will no longer pay doctors to promote its products/drugs, the company's office in India said that the changes will be in place across GSK's global business, including India.

**Publication:** The Hindu Business Line

**Edition:** National

**Date:** December 19, 2013

**Headline:** [Pharma market climbs out of sales trough](#)

**Synopsis:** The Indian pharmaceutical market scrambled out of a three-month lull to achieve a 2.5 per cent sales growth in November over the corresponding period last year. The revival, brought by stockists raising supply and higher business in select therapies, comes after overall volumes shrank during August-October, the period when a Government order on capping rates of 348 essential medicines began to take effect. As a result, drug makers are grappling with sluggish price growth, which stood at 0.8 per cent, said a study by market research

firm AIOCD Pharmasofttech AWACS. After the Drug (Prices Control) Order 2013 capped medicine prices in early August, stockists and retailers protested a cut in margins imposed by manufacturers to make up for lower selling prices.

**Publication: Firstpost**

**Edition: Online**

**Date: December 19, 2013**

**Headline: [FDA, European regulators to cooperate on generic drugs](#)**

**Synopsis:** US and European drug regulators will work together on joint inspections around the world to try to make sure consumers are buying generic medications that are both safe and effective, the US Food and Drug Administration said on Wednesday. The European Medicines Agency and France, Germany, Italy, the Netherlands and the United Kingdom are taking part in the initiative, which will focus on the testing stage that precedes generic drug applications. They will cooperate on inspecting facilities used in clinical trials and assess the acceptability or reliability of data obtained in the trials. A pilot phase of the program will begin on January 2.

**Publication: Pharmabiz**

**Edition: Online**

**Journalist: Suja Nair Shirodkar**

**Date: December 19, 2013**

**Headline: [Pharmacists urge DCGI to issue clarifications on Schedule H1 to avoid misinterpretation](#)**

**Synopsis:** Pharmacists across the country have expressed huge concern over the lack of clarity in the recently published gazette notification on Schedule H1, which deals with regulating the use of antibiotics in the country. Raj Vaidya, a community pharmacist, points out that there are lot of gray areas in the notification that needs to be clarified so as to avoid complications arising due to misinterpretation of some clauses by different persons or authorities.

**Publication: Pharmabiz**

**Edition: Online**

**Journalist: Joseph Alexander**

**Date: December 19, 2013**

**Headline: [New panel to suggest guidelines for verifying over 5000 FDCs approved without DCGI clearance but still in market](#)**

**Synopsis:** Over 5000 fixed dose combinations, which were not approved by the Drug Controller General of India (DCGI) in respect of their safety and efficacy but granted licenses by the state licensing authorities, continue to be sold in the market, even as the regulatory authorities are now grappling with the question of how to verify them. After the DCGI issued notices the manufacturers to submit safety data, as many as 5000 applications were received by his office, and many of them were found to be having no therapeutic justification or rationality for their marketing in the country, it is learnt.

**Publication: Pharmabiz**

**Edition: Online (Editorial)**

**Date: December 19, 2013**

**Headline: [Generic Export Under Threat](#)**

**Synopsis:** Last week Indian pharmaceutical industry received yet another blow to its reputation from the US FDA when it charged Wockhardt Ltd of manipulating data related to production trials of drugs at its two Indian factories, which had earlier been banned from shipping medicines to the US. The Wockhardt factories located at Waluj and Chikalthana in Maharashtra had to halt exports to the US sometime ago. The US FDA in a letter to the company stated that the lack of reliability and accuracy of data generated by Wockhardt's laboratory is a serious cGMP deficiency that raises concerns about the integrity of all data generated by the company. Data integrity issues at drug manufacturing plants attract severe penal action from the US FDA and other international regulatory agencies. The US regulator further said that the company had not only violated

standards of manufacturing practices but also misguided the regulator. These are serious charges on a company like Wockhardt which earns a substantial part of its revenue from exports to various developed markets and the US is perhaps the most important destination among them.

### Patents

**Publication:** The Times of India

**Edition:** National

**Journalist:** Rupali Mukherjee

**Date:** December 19, 2013

**Headline:** [Patent war spills over to non-cancer drugs](#)

**Synopsis:** The turf war between Big Pharma and generic companies, which was largely restricted to exorbitantly priced drugs for cancer and HIV, is now spilling over to chronic and lifestyle problems. In yet another instance of a drug MNC losing monopoly, the Chennai Patent Office, an opposition filed by Ranbaxy, has revoked Pfizer's patent on a drug used in urinary incontinence, which is expected to bring down its price substantially. Significantly, the revocation of the patent may challenge Pfizer's claims of monopoly on the Detrol formulation, experts say. The patent office recently revoked Pfizer claims on patent exclusivity for a formulation of its best-selling drug Detrol, used to manage overactive bladder symptoms.

### Vaccine

**Publication:** The Times of India

**Edition:** Chennai

**Date:** December 19, 2013

**Headline:** [3 infant deaths linked to vaccine: Govt](#)

**Synopsis:** Of the four infants who died last year in Tamil Nadu after receiving pentavalent vaccine, three deaths have been linked to the shots, the Union health ministry has admitted in reply to an RTI query. The three deaths in the state had a "consistent causal association to immunisation," it said, observing that the fourth death was "unclassifiable" owing to lack of information. The government has culled the information on children's death from the latest causality assessment report of the national adverse events following immunisation (AEFI) committee, which investigated 20 deaths since the pentavalent immunisation started in 2011. Of these, 13 were from Kerala, four from Tamil Nadu and three from Haryana.

**Publication:** The Hindu

**Edition:** Noida/ Delhi

**Date:** December 19, 2013

**Headline:** [Potential malaria vaccine discovered](#)

**Synopsis:** Researchers have discovered a key process during the invasion of the blood cell by the Malaria parasite, and have found a way to block this invasion. With this new knowledge, the scientists from Singapore's Nanyang Technological University (NTU) are looking to collaborate with the industry on a vaccine against malaria which can be developed within the next five years if accelerated by vaccine development companies. Lead scientist Professor Peter Preiser said his team's scientific breakthrough will be instrumental in paving the way towards eradicating Malaria in the long run.

### General Industry

**Publication:** The Times of India

**Edition:** Bangalore

**Journalist:** Anshul Dhamija

**Date:** December 19, 2013

**Headline:** [Biocon to tackle glaucoma through global tie-up](#)

**Synopsis:** Indian biopharmaceutical major Biocon has expanded its therapeutic portfolio with the addition of ophthalmology through a licensing and collaborative partnership with the US-based Quark Pharmaceuticals. The

tie-up gives Biocon rights to co-develop, manufacture, and commercialize QPI-1007, a novel drug for the treatment of ophthalmic conditions such as glaucoma, in India and other markets. Biocon has a strong pipeline of drugs, both under development and in the market, in the therapeutic areas on diabetes, oncology, and autoimmune disease. Glaucoma, characterized by the progressive loss of vision, is the leading cause of blindness worldwide. In India, it is estimated that glaucoma affects 12 million people, which by the end of the decade would increase to 16 million.

Similar report appeared in

Business Standard: [Biocon, Quark tie up to develop eye drug](#)

The Economic Times: [Biocon inks licensing pact with US-based Quark Pharma](#)

**Publication: The Times of India**

**Edition: Hyderabad**

**Date: December 19, 2013**

**Headline: [New study finds high prevalence of hypothyroidism in Hyderabad](#)**

**Synopsis:** A study funded by a pharma major on the prevalence of the thyroid disorder claims that about one in 10 persons in the city suffers from hypothyroidism. The 'Thyroid Epidemiological Study' funded by Abbott was conducted in eight cities, including Bangalore, Chennai, Delhi, Goa, Ahmedabad, Kolkata and Mumbai, besides Hyderabad with a total sample of 5,360. "Approximately, 9% of the study population (383 persons in the twin cities ) reported hypothyroidism in Hyderabad. About 50% were oblivious of their medication condition. Additionally, about 24% of the population tested positive for antibodies that puts them at a higher risk of developing hypothyroidism in the future," said Dr Loy Camoens, physician, Healing Touch Hospital, at a media conference organized to release the data on Hyderabad.

**Publication: The Times of India**

**Edition: New Delhi**

**Journalist: Durgesh Nandan Jha**

**Date: December 19, 2013**

**Headline: [Weight-loss surgery free for babus](#)**

**Synopsis:** The growing demand for weight-loss surgeries from sarkari babus has forced the Centre to include the procedure, long considered a lifestyle choice, in the central government health scheme (CGHS) list. It will now be available free of cost to those covered under the government scheme at select hospitals. According to the Union health ministry, guidelines of the US National Institute of Health will be used for select candidates for the procedure. The government has fixed a package rate of Rs 2.25 lakh per person for such a surgery. In India, an estimated 200 million people suffer from weight-related issues. According to Dr Praveen Bhatia, executive member of Obesity Surgery Society of India, close to 2,000 persons undergo weight loss surgery every year. Bariatric surgery involves stapling of a portion of the stomach to reduce a person's appetite.

**Publication: The Economic Times**

**Edition: Online (PTI)**

**Date: December 19, 2013**

**Headline: [Lupin launches HIV drug in the US with marketing exclusivity](#)**

**Synopsis:** Drug major Lupin said it has launched the generic version of ViiV Healthcare's (ViiV) Trizivir tablets in the US market with 180-days of marketing exclusivity. The company said its US subsidiary Lupin Pharmaceuticals Inc has launched Abacavir Sulfate, Lamivudine, and Zidovudine tablets in the US market after the US District Court for the District of Delaware ruled that Lupin's generic version of Trizivir did not infringe on patents, Lupin said in a statement.

**Publication: The Financial Express**

**Edition: National**

**Journalist: P P Thimmaya**

**Date: December 19, 2013**

**Headline: [Healthcare, telecom & media businesses will drive growth](#)**

**Synopsis:** Firstsource Solutions, the \$500-million business process outsourcing company and part of the RP-Sanjiv Goenka Group, is confident of achieving an operating profit margin of 14-15% from FY15 driven by the US healthcare market and stronger overall demand. In an interview with PP Thimmaya, Firstsource managing director and CEO Rajesh Subramaniam said the turnaround has begun with the company getting measured by its customers for generating value and not just lowering costs. Edited excerpts.

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

**Edition: National**

**Date: December 19, 2013**

**Headline: [Par panel calls for creation of Central Drugs Administration](#)**

**Synopsis:** Parliamentary panel has recommended creation of a professionally-managed Central Drugs Administration to check malpractices in drug manufacturing after rejecting the proposal for the setting up of a Central Drugs Authority under the amended Drugs and Cosmetics Act. In its report on the Drugs and Cosmetics (Amendment) Bill, 2013, the Parliamentary Standing Committee on Health has said that there is a need for effective discharge of enforcement activities which requires a strong, professionally-managed administration which can take action against unscrupulous manufacturing companies.

**Publication: Pharmabiz**

**Edition: Online**

**Journalist: Peethaambaran Kunnathoor**

**Date: December 19, 2013**

**Headline: [Medicinal plant cultivators aggrieved for not finding solutions to their grievances & unfair treatment by big cos](#)**

**Synopsis:** Even as the 'Oushadha Keralam-2013', the ayurveda trade expo organised by State Medicinal Plant Board (SMPB) and the Ayurveda communities in Kerala, has attracted a number of manufacturers and showcased a variety of products in the ancient system of treatment, the farmers of medicinal plants in Kerala remained an aggrieved lot for not finding any solution for their grievances and the unfair treatment they receive from big manufacturing companies, it is learnt.

**Publication: The Financial Express**

**Edition: Online**

**Date: December 19, 2013**

**Headline: [Buy Cipla shares on growth prospects](#)**

**Synopsis:** Cipla has received approval to sell Levabuterol HCL inhalation solution, the generic version of Xopenex. We expect the company to garner \$5-6 million from the transaction, assuming 80% price erosion and 10% market share. Maintain 'buy' with target price of R495, valuing 20x September FY15E EPS. The drug's total market size is \$315 million and there are four generic players, including Teva, Mylan, Actavis and Dey Pharma. Cipla has a pipeline of 35 pending approvals, including six own Abbreviated New Drug Application (ANDAs) and it has taken back 20 ANDAs from partners to ramp up its presence in the US.