



**News Updates: November 16-20, 2013**

**Patents / Intellectual Property Rights / Compulsory Drug Licensing**

**Publication: The Economic Times**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Why you should stay invested in stocks with growth potential like IT, pharma and FMCG](#)**

**Synopsis:** Technology, pharma and FMCG stocks have moved up sharply in the last one year. Technology and pharma companies were riding on the back of rupee depreciation and a recovery in the US market, while investors have found safety in the FMCG sector due to its reputation as a 'safe haven' against high inflation and interest rates. There is earnings visibility in sectors such as pharma, FMCG. Pharma companies will benefit due to huge generics opportunities in the US, while FMCG companies continue to benefit because of margin expansion," says Alok Ranjan. Patents worth \$73 billion will expire in 2013-2016, and it is a major positive factor for generic drug makers.

**Publication: Business Standard**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Attn Netas, India Inc.- Pay heed to CNR Rao's angry outburst](#)**

**Synopsis:** Ranbaxy Laboratories spent 9.7% in research in 2007/08, that's down to 4.2% in 2011/12. No surprise then that India has severely lagged behind in filing patents. Only about 6,000 patent applications were filed by Indians in 2010, which is a mere 0.3% of the total applications filed in the world. Moreover India has steadily seen a decline in its position on the world innovation map - dropping to the 66th position this year from 23rd in 2007-08 on the Global Innovation Index.

And yet, despite lack of support from the government and big home grown businesses sleeping on the need for more research, scientists have managed a feat of sorts, as Rao rightly pointed out. MNCs have extended support, with 870 of them establishing R&D centres in India. And grassroots initiatives have seen an explosion notwithstanding the funding crunch. The National Innovation Council recently claimed it had listed 1,75,000 innovation practices in India over the last couple of years, busting repeated claims that Indians do not ascribe too much value to innovation, focusing only on jugaad.

**FDI**

**Publication: The Financial Express**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Allow only 49% FDI in critical brownfield pharma units: DIPP](#)**

**Synopsis:** The Union Cabinet is likely to consider the revised policy on foreign direct investment (FDI) in the pharma sector this week with the industry department proposing that one-fourth of investments in brownfield projects be used in research and development activities. While maintaining that 100 per cent foreign direct investment should be allowed in brownfield projects, the Department of Industrial Policy & Promotion (DIPP) has, however, stated that if the projects deal with rare facilities and critical verticals, only 49 per cent FDI should be allowed with the government approval, an official told The Indian Express.

**Publication: The Telegraph**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Debate on drug FDI](#)**

**Synopsis:** The Union cabinet remains divided on the steps to curb the foreign takeover of Indian drug firms that are major players in the generic market. The finance ministry and the Planning Commission are in favour of fewer curbs, but the health ministry and the department of chemicals want to restrict foreign investment. Opponents to takeovers by MNCs feel the subsequent control of the market and possible price increases can raise the cost of healthcare not only in India but also in developing countries where Indian generic medicines are sold in large quantities.

**Publication: India Briefing**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [India Mulls Pharmaceutical Sector Investment Cap](#)**

**Synopsis:** After a controversial acquisition earlier this year, India is considering strict new limits on foreign investment in the pharmaceutical industry. According to a senior government official who spoke with the Wall Street Journal under condition of anonymity, the proposal currently under review would prohibit foreign companies from owning more than a 49 percent stake in Indian manufacturers of "rare and critical" medicines. Under the existing law, foreign investors are permitted to buy 100 percent of local drug companies. This February, U.S.-based Mylan Inc.'s acquisition of Agila Specialties Pvt. Ltd. – a local manufacturer of antibiotics and chemotherapy drugs – provoked outrage among Indian politicians who viewed the acquisition as a threat to domestic drug supply. Because India controls some drug prices domestically, many argued the acquisition could result in critical Indian-made pharmaceuticals being exported to more profitable markets – thereby endangering local access to inexpensive, lifesaving medicines.

#### FDA / Drug Regulatory / DCGI

**Publication: The Economic Times**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Ranbaxy whistleblower Dinesh Thakur wants strong policy to unearth fraud](#)**

**Synopsis:** Dinesh Thakur, the former Ranbaxy executive who famously exposed dubious manufacturing practices at his employer and pocketed \$49 million from the US authorities, has said that the Indian government must put in place a robust structure to protect whistle-blowers if it wanted more corporate frauds to be unearthed. If we want corporate frauds in the country to be reported, the government must ensure a strong framework for whistleblower protection, both in terms of the information and individual sharing it, Thakur told ET.

**Publication: Pharmabiz**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [Drug procurement through CMSS to start soon with govt making it operational](#)**

**Synopsis:** The keenly-awaited Central Medical Services Society (CMSS), looking to streamline the sensitive drug procurement system, has been made formally operational with the Union Health Ministry issuing the final notification to spell out the details including the system of procurement of medicines. The drug procurement through the CMSS for different flagship programmes under the Central government is expected to start with this. The Government had already appointed the director general and other key persons to run the organisation which will look to eliminate deficiencies in the existing system of purchasing medicines, vaccines, contraceptives and medical equipments for all government's flagship programmes. At present, the ministry is procuring drugs departmentally and through agents, drawing flaks and raking controversies at regular intervals.

**Publication: Pharmabiz**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [PMS & Drug Safety](#)**

**Synopsis:** Adverse drug reactions of most new drugs will be fully known only when they are launched in the market and lakhs of patients start using them. Post marketing surveillance and regular monitoring ADRs of drugs is, therefore, critical for the health authorities to decide their total safety. Pharmaceutical companies normally do not carry out PMS or Phase IV studies even though such studies are mandatory in several countries including India. Although submission of post marketing surveillance data is mandatory on the pharmaceutical companies, most of the companies do not care to submit such reports to the DCGI. The Parliamentary standing committee on health & family welfare had recently taken serious note of this deficiency in enforcement of this rule by the office of the DCGI.

### Drug Pricing

**Publication: Business Standard**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [Gujarat pharma cos post growth in Oct as overall industry growth dips](#)**

**Synopsis:** The Drug Price Control Order 2013 segment of GlaxoSmithKline (GSK) degrew by 48.9 per cent, while for Ranbaxy is degrew by 31.9 per cent. Coming to segments, the cardiac segment has done well in Gujarat with a MAT growth of 9.8 per cent, while anti-diabetic growth was at 8.2 per cent, hormones at 10.3 per cent and respiratory at 9 per cent.

**Publication: The New Indian Express**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [Jan Aushadhi scheme yet to take off](#)**

**Synopsis:** The State Government's claim to provide generic medicines to the poor at subsidised rate under Centre-sponsored Jan Aushadhi scheme has been proved wrong as the only store set up on the premises of the District Headquarters Hospital still remains defunct. As per Government's claim, the poor patients were to be provided generic medicines at a price as low as one-tenth of the prevailing market rate through drug stores established under Centre-sponsored Jan Aushadhi scheme.

**Publication: MoneyLife**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [NLEM: Grey area about what are "essential drugs"](#)**

**Synopsis:** While market based pricing can potentially reduce pricing for two-third essential medicines, there are several critical medicines that are not in the "essential medicines" list. Several Diabetes, TB, HIV, Cancer drugs are not under DPCO 2013 even though WTO lists them as essential. According to Drug Price Control Order (DPCO) 2013, the ceiling of prices is fixed based on the simple average of the prices of all brands of that drug that have a market share of at least 1%. The national list of essential medicines lists 348 bulk drugs, which are sold as 650 formulations. DPCO 2013 itself covers only 14 %-17% of the Rs75,000 crore pharma market, which means only a small subset of the market will be impacted. It is bizarre that many "essential" medicines are actually not in the current National List of Essential Medicines (NLEM) 2011. What constitutes "essential" and "unessential" drugs should not be much of a debate.

## Clinical Research / Trials

**Publication:** The Hindu Business Line

**Edition:** National

**Date:** November 20, 2013

**Author:** S. Srinivasan, LOCOST, Vadodara, and All-India Drug Action Network

**Headline:** [A muddled view of clinical trials](#)

**Synopsis:** The Ranjit Roy Chaudhury report seems ambivalent about the dangers. In light of the controversy surrounding the conduct of clinical trials in India, the government appointed an expert committee chaired by Prof. Ranjit Roy Chaudhury (hereafter the RRC Report) to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The report of the committee has been in the public domain for some three months now. Earlier this month, the Government, in an act of unusual efficiency, came out with a note on actions taken on the recommendations – without formally taking feedback from the stakeholders.

**Publication:** Business Standard

**Edition:** National

**Date:** November 20, 2013

**Headline:** [Avesthagen, Elpen in pact](#)

**Synopsis:** Avesthagen Pharma AG (APAG) has announced an agreement with Elpen Pharmaceutical Co. Inc., a company from life-sciences, for the distribution of Avdesp, a biosimilar product in seven EU and six non-EU territories including Greece, Cyprus, Bulgaria, Romania, Croatia, Slovenia, Slovakia, Serbia, Bosnia, Macedonia, Albania, Montenegro and Kosovo with a collective population base of over 70 million. The present global sales for the product are in excess of \$2.5 billion and APAG hopes to price Avdesp for it to come within the reach of a wider global community. APAG is presently engaged with many other opportunities for a number of its 'biosimilars' and 'biobetters' with strong principals in several countries. APAG is working with different outsourcing organisations to make sure the product come to the market at the earliest. APAG has identified Syngene International for fill and finish, and Kemwell Bioharma as a CMO (Contract Manufacturing Organization). and PRA International, a global CRO to conduct the carry out the Phase I Clinical Trial in The Netherlands followed by Phase III in India.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 20, 2013

**Headline:** [IPA WB branch urges govt to immediately implement Prof Chaudhuri report on clinical trials](#)

**Synopsis:** The Indian Pharmaceutical Association (IPA), West Bengal branch has urged the union health ministry to initiate immediate steps to implement the recommendations made by Prof Ranjit Roy Chaudhuri expert committee as it will go a long way in protecting the rights of the subjects in clinical trial. IPA West Bengal branch vice president Dr Subhash Mandal said that though the government has accepted in-principle the report of Prof Chaudhuri committee, the government is yet to take any concrete step to implement the recommendations in letter and spirit. The government should implement the recommendations urgently as the whole procedure of the clinical trials needs to be changed and the rights of the subjects have to be protected. The Chaudhuri committee report will help solve all these issues, he said.

## General Industry

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 20, 2013

**Headline:** [Health Min plans to tap potential of social marketing to scale up healthcare delivery](#)

**Synopsis:** The Union Health Ministry plans to tap the possibilities of social marketing (SM) and social

franchising (SF) as effective tools to reach out to the rural population and scale up healthcare delivery under its flagship programmes, said Anuradha Gupta, additional secretary of Health and mission director of National Rural Health Mission. Addressing a press conference she said, with a view to garner the inputs from thought-leaders around the world and chalk out a concrete plan for India after deliberating on global best practices, a first of the kind global meet of health experts will be held in Kerala from December 3 to 5.

**Publication: Medianama**

**Edition: Online**

**Date: November 20, 2013**

**Headline: [Healthkart Plus Expands Operations To Bangalore](#)**

**Synopsis:** HealthKartPlusOnline generic drug search engine HealthKartPlus.com, owned by online health store HealthKart has expanded its operations to Bangalore. Previously available only in Delhi-NCR region, the website also allows consumers to purchase drugs through its marketplace and have it home delivered. Following Bangalore launch, the company plans to expand this service to other metros in a phased out manner. It is worth noting that the company is only facilitating the buying process while the pharmacies are the ones selling the drugs online. The company had in fact launched HealthKart Plus as a marketplace to avoid any regulatory issues that may arise from the online sale of prescribed drugs.

### Innovation

**Publication: Hindustan Times**

**Edition: National**

**Date: November 20, 2013**

**Author: Op-Ed - Sudhirendar Sharma researches development issues at The Ecological Foundation, New Delhi**

**Headline: [The inconvenient fact of drug resistance](#)**

**Synopsis:** In 2011, a fifth of the global human population perished on account of infectious diseases. With the power of anti-microbial and anti-bacterial drugs literally coming to an end, some 9.5 million people in developing countries paid the price for the growing resistance of bugs. The only way to pull out of the crises, according to Davies, is to make drug innovation financially attractive. If a \$10 million Ansari X Prize can be created to stimulate research on new generation of space launch vehicle, setting up a \$50 million prize for anyone discovering a new class of antimicrobial drugs can surely go a long way towards saving millions of people from the danger of emerging infections.

**Publication: [The Economic Times](#) and Daily News and Analysis**

**Edition: National**

**Date: November 20, 2013**

**Headline: [Innovation critical to enhance India's competitive edge: Pranab Mukherjee](#)**

**Synopsis:** India's biggest strength will be its demographic dividend, President Pranab Mukherjee said on Tuesday and noted that innovation was critical to enhance country's competitive advantage in an increasingly globalised world. "Innovation is crucial to enhance competitiveness in an increasingly globalised world. In Indian context, it is critical," the president said. He said innovation should be used to meet challenges in sectors such health, education and housing. He said innovation should be applied "not only to generate solutions but to make development process more inclusive."

### Patents / Intellectual Property Rights / Compulsory Drug Licensing

**Publication: Business Standard (Opinion Editorial)**

**Edition: National**

**Date: November 19, 2013**

**Headline: [Troubles with trade](#)**

**Synopsis:** Some in the Indian pharmaceutical sector, however, will object to the wording of the proposed draft with respect to patents and generic drugs and active pharmaceutical ingredients that go into making them. The organisation Doctors Without Borders/Medecins Sans Frontieres, which has often allied with India's generic pharmaceutical industry, has claimed that the treaty, if implemented in its present form, will extend the monopoly protection of high-priced pharmaceuticals and delay the entry of affordable medicines by facilitating "evergreening" through incremental patenting. If such provisions gain ground, the role of Asian countries like India as global suppliers of generic drugs is likely to be jeopardised. It is also feared that this could harm the Indian pharmaceutical industry's capabilities in bolstering its export earnings and supplying affordable medicines to the poor. The Indian legal system protects IPR to reward innovation while preventing unjustified extension of patents. However, the Indian legal system has been a global outlier in this area. Thus, the TPP taking a different direction should not be a complete surprise.

**Website:** MoneyControl

**Edition:** National

**Date:** 18.11.2013

**Headline:** [Patent win against Teva to boost revenues: Natco Pharma](#)

**Synopsis:** With the company having won the patent case against Teva Pharmaceuticals enabling them to launch the generic drug for multiple sclerosis (Copaxone), Bhaskar Narayana, Finance Director & CFO, Natco Pharma feels it will help boost the topline and bottomline of the company because size of the market for the drug is very big.

#### FDI

**Publication:** The Economic Times

**Edition:** National

**Date:** November 19, 2013

**Headline:** [FDI in pharma sector doubled during April-August](#)

**Synopsis:** Foreign direct investment in the pharma sector has more than doubled to \$ 1.07 billion during April-August period amid concerns over increasing acquisitions of domestic firms by multinationals. FDI in drugs and pharmaceuticals was \$ 487 million during April-August 2012, according to the latest data of the Department of Industrial Policy and Promotion ( DIPP).

**Publication:** The New Indian Express

**Edition:** National

**Date:** November 19, 2013

**Headline:** [India Inc strikes PE deals worth \\$8.9 bn in Jan-Oct](#)

**Synopsis:** Indian Inc signed about 360 Private Equity (PE) deals aggregating to \$8.9 billion in the January-October period this year, registering an increase of 33 per cent as against 345 transactions worth \$6.7 billion during the corresponding period a year ago. While the top five deals accounted for 63 per cent of the total PE deal values, IT and ITeS space garnered over 34 per cent of the total deals with the sector witnessing 18 deals worth \$281 million, followed by pharma, healthcare (26% with \$216 million), real estate (22%, \$177 million), retail (7%, \$56 million) and media and entertainment (4%, \$30 mn).

#### FDA / Drug Regulatory / DCGI

**Publication:** Business Today

**Edition:** National

**Date:** November 19, 2013

**Headline:** [FDA for greater freedom to generic firms](#)

**Synopsis:** US drug regulator Food and Drug Administration (FDA) plans to allow generic drug makers, including those from India, to independently update product labelling when they discover new safety data, a move which can bring them on par with branded medicine manufacturers. Generic manufacturers, which make cheaper but therapeutically equivalent versions of innovative drugs, would be required to inform the brand name manufacturer about the labelling change. The US market is home to generic drug spending of about \$ 300 billion every year and India produces nearly 40 per cent of generic and over-the-counter products while its share in the finished dosage medicine segment is about 10 per cent.

**Publication:** Daily Bhaskar

**Edition:** National

**Date:** November 19, 2013

**Headline:** [Suspicious and dangerous drugs sold in Indian markets may soon be reviewed and restricted](#)

**Synopsis:** Professor Ranjit Roy Chaudhury Committee is in talks with Ministry of Health to impose restrictions on suspicious drugs in India by appointing an Expert Committee to review potentially dangerous drugs on the health front. Detected drugs shall be restricted with the help of a mechanism shall be developed under the Central Drug Standard Control Organisation.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 19, 2013

**Headline:** [Eight kids die in Kashmir due to suspected adverse events of pentavalent vaccine](#)

**Synopsis:** Even as the union health ministry is going hammer and tongs in introducing the controversial pentavalent vaccination in more and more states in the country despite reservations expressed by experts on the safety of the vaccine, eight infants died in Kashmir due to suspected adverse events following pentavalent vaccination. The deaths were reported between September and October this year. The pentavalent vaccine for protection against five childhood diseases was introduced in Jammu & Kashmir in February 2013, as part the universal immunization programme (UIP). Three doses of this vaccine replace the conventional DPT vaccine which protects against three diseases, diphtheria, pertussis (whooping cough) and tetanus. The newer pentavalent vaccine includes the DPT as well as vaccines against pneumonia-meningitis (Hib) and hepatitis B. It had been discontinued in Vietnam in May for these reasons and was re-started in October, following which adverse reactions were once again reported. It is being used largely in several developing countries only and is not licensed for use in the USA by the US FDA. This vaccine is being promoted vigorously by several international agencies, specifically World Health Organization (WHO) and the Global Alliance for Vaccines and Immunization (GAVI), an international network of vaccine manufacturers and philanthropic organizations such as Gates Foundation.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 19, 2013

**Headline:** [KSRPA approaches ministries of C&F and Health for new amendments in D&C Act 1940](#)

**Synopsis:** Karnataka State Registered Pharmacists Association (KSRPA) has called for new amendments in the Drugs and Cosmetics (D&C) Act 1940 and additional revisions to D&C Rules 1945. "These amendments are for the effective day-to-day implementation of the Act and in the interest of the public," said Ashokswamy Heroor, president, KSRPA. Heroor said that these were needed to transform the pharmacy trade, manufacturing and marketing in India.

#### Clinical Research / Trials

**Publication:** Financial Times

**Edition:** Online

**Date: November 18, 2013**

**Journalist: Amy Kazmin in New Delhi and Andrew Jack in London**

**Headline: [India ruling on drug trials injects fears for industry's health](#)**

**News Report:** For nearly a decade, Biocon, a Bangalore-based pharmaceutical company, has been working to develop an insulin pill – the “holy grail” of diabetes treatment – that could revolutionise the lives of millions of diabetics who every day inject themselves with the hormone. It is a market, potentially worth \$18bn year, also being chased by Denmark’s Novo Nordisk, the world’s largest insulin product producer, and Israel’s Oramed Pharmaceuticals. But Biocon, which has an agreement with Bristol-Myers Squibb for developing its oral insulin treatment, this year hit an unexpected roadblock: Indian regulatory turmoil that has brought clinical drug trials in the country to a virtual standstill. In response to a public interest lawsuit by activists complaining of global drug companies using Indians as “human guinea pigs”, New Delhi this year laid out tough rules that make companies liable for any drug trial subject’s injury or death – whether caused by the study or not. The Supreme Court suspended 157 previously approved clinical trials, pending review by new committees. Approvals for new drug trials have slowed dramatically, due to the newly created multi-level approval process, and bureaucrats’ fears of giving go-aheads for trials that may later prove controversial. As a result of the ruling, western and Indian drug companies have been forced to cancel or suspend hundreds of clinical trials – including some backed by the US’s National Institutes of Health. Industry executives say the rules have cut Indian patients’ access to new therapies, and are threatening the competitiveness of local drug companies, including their efforts at original research. “If India wants to be the pharmacy of the world, you have to have clinical research,” says Kiran Mazumdar-Shaw, Biocon’s chairman and managing director. “Just because a few companies may not have followed the norms, they have taken this drastic action against all companies. This is a knee-jerk reaction.” Mahima Datla, managing director of Hyderabad-based vaccine producer Biological E, which has had several clinical trials delayed, says the action “will kill drug development in India. Companies will do their studies elsewhere and it is the Indian consumer who will suffer.” India carried out about \$450m worth of clinical drug trials in 2010-11, and the total was expected to grow to \$1bn by 2016. Growth was fuelled partly by global drugmakers seeking low-cost centres to test new medicine, while many Indian pharmaceutical companies set up units to facilitate studies by foreign players.

But drug trials were also increasing because of the rising international ambitions of India’s own domestic pharmaceutical industry, which last year exported \$13bn of medicines. Most Indian drug exports are low-cost generic versions of patented medicines already widely used in the west, but their makers must also carry out clinical trials to prove their drugs are as safe and efficacious as the original before selling in western markets. Indian drugmakers such as Biocon, Zydus Cadilla, Glenmark and Sun Pharma, are also pushing into innovative drug research and development, hoping to create globally groundbreaking new medicines – aspirations that could be set back by ponderous restrictions on clinical trials. On paper, industry executives say, India’s rules for clinical drug trials were already consistent with international standards. But the severely understaffed regulating agency failed to monitor trials on the ground adequately. Amulya Nidhi, an activist with the Swasthya Adhikar Manch (Health Rights Forum), the group that filed the public interest lawsuit against clinical tests, says many drug trials in India have exploited the desperation of poor patients, who cannot afford to buy proven medicines and are instead offered free drugs under a study – without realising the medicine is still being tested. “They enrol and they are not even given consent forms,” Mr Nidhi says. Indian health officials told the Supreme Court that 2,500 Indian drug trial participants died between 2005 and 2012, but said just 80 of the deaths were linked to the tests. However, activists say that many deaths were never properly investigated. Mr Nidhi also said most Indians who suffered injury as a result of the drug trials were not compensated, or received only tiny sums of money. DG Shah, head of the Indian Pharmaceutical Alliance, which represents India’s leading drug companies, says that clinical trials in India have not always met international standards, but adds that the new rules are threatening to stifle such tests. “Certain excesses were committed which did not take care of patient interests,” he says. “This is a backlash against that. But the pendulum has swung to an extreme.” Quintiles, a US-based clinical research organisation that carries out drug tests for the global pharmaceutical industry, says it has scaled back its Indian operations, while GlaxoSmithKline says it is “pausing patient enrolment” into clinical trials. Local generics companies are switching studies to countries including Bangladesh, Malaysia and the Philippines. But with the industry in an uproar, New Delhi is re-examining the new rules to ensure that they do not stifle the prospects of domestic drug companies. Suresh Jadhav, executive director of the Serum Institute of India, has called the new rules “ridiculous”, but says changes and clarifications in response to industry concerns are expected in the next few months. Mrs Mazumdar-Shaw says she is optimistic that the issue will be resolved, though Biocon is relocating the Indian portions of its oral insulin trial elsewhere, in spite of higher costs. Global interest in

India as a stage for clinical drug trials may remain muted, however. New Delhi has indicated that foreign companies testing new drugs in India must ensure the medicines will subsequently be made accessible to Indian patients – linking clinical trials to the fraught issue of the high prices of patented drugs.

**Publication: Financial Times**

**Edition: Online**

**Date: November 18, 2013**

**Journalist: Amy Kazmin in New Delhi**

**Headline: [Vaccination scandal taints reputation of India drug trials](#)**

**News Report:** About 72,000 Indian women die each year of cervical cancer, a disease caused by the human papillomavirus. Many of these deaths are preventable by vaccines already widely used in the US, Australia and Europe, and included in their recommended immunisation protocols. In 2009, Path, a US-based health charity, launched a project funded by the Bill and Melinda Gates Foundation to study the cost and feasibility of incorporating HPV vaccines, produced by Merck and GlaxoSmithKline, into India's public sector immunisation programme. However, the programme to vaccinate 14,000 adolescent girls from poor families ran into trouble after seven died soon after their vaccinations. The ensuing media and political storm – highlighting sensitivities around drug trials in the developing world – has contributed to the restrictions on such studies, affecting both Indian and global pharmaceutical companies. The causes of the girls' deaths were never established or conclusively linked to the HPV vaccine. But serious questions were raised over whether the participants' parents – many of whom were illiterate – had given informed consent, and whether the project adequately tracked any adverse reactions. In August, an Indian parliamentary committee set up to probe the issue concluded the Path project was a clinical trial in all but name and that the organisation had used "subterfuge" to avoid the "arduous and strictly regulated process" of such a trial. The committee report said many of the girls' consent forms had apparently been signed by school principals and hostel wardens, and expressed scepticism that the girls' parents were fully briefed on the pros and cons. The committee also found there was no rigorous process to track adverse events, leading to "gross underreporting". It came down hard on Indian government agencies for alleged dereliction of duty. "The safety and rights of the children in this vaccination project were highly compromised and violated," the report said. It also claimed that Path's "sole aim was to promote the commercial interests of HPV vaccine manufacturers, who would have reaped windfall profits had Path been successful in getting the HPV vaccine included" in India's immunisation protocols. Path called the parliamentary report an "inaccurate characterisation of this important work" and said it disagreed with its "findings, conclusions and tone". The organisation said the HPV project was driven by its belief that "poor and low-income girls in India should not be deprived of the right or access to this proven, life-saving and safe vaccine that wealthy and middle-class girls in India and around the world have access to through the private market and other public immunisation programmes".

#### Clinical Research / Trials

**Publication: Deccan Chronicle**

**Edition: National**

**Date: 19.11.2013**

**Headline: [Centre for filming clinical trials](#)**

**Synopsis:** The Union health ministry has proposed mandatory audio-visual recording of participants in clinical trials, making it tougher for drug companies to shrink responsibility when testing of their medicine reacts adversely on patients. Significantly, the new recommendations by a panel headed by Medical Council Of India (MCI) member Prof Ranjit Roy Chaudhury, the investigator can be debarred from clinical trials in case a violation is witnessed on their part.

**Publication: The Pioneer**

**Edition: Delhi**

**Date: 19.11.2013**

**Headline: Health Ministry to cap clinical trials** *(No link available)*

**Synopsis:** The Union health Ministry has decided to restrict medical practitioners from conducting more than three clinical trials at a time in the country. There have been allegations that private doctors have been taking up clinical trials in a large number as profitable business ventures ignoring science and the rights of patients. The proposed step to put a cap on clinical trials come close on the heels of the Drug Controller General of India (DGCI)s move to make it mandatory for pharma companies and sponsors to disclose the financial support or payments made to the clinical investigators or medical practitioners for conducting clinical experiments.

**Publication: Pharmabiz**

**Edition: National**

**Date: 19.11.2013**

**Headline: [Health ministry plans changes in rules to ensure ancillary care to trial victims](#)**

**Synopsis:** The Health Ministry will effect changes in rules to bring in further clarity to the compensation norms to the victims of clinical trials and provisions for ancillary care in line with the suggestions by the expert panel, though the legislation is underway by way of the bill to regulate the clinical trials sector.

Pressured by the ongoing cases in the Supreme Court over the clinical trials regulatory framework, the Ministry is planning to amend the rules through gazette notifications or executive orders to bring in the changes instead of waiting for the passage of the Drugs and Cosmetics (amendment) Bill, 2013 which is under the consideration of the Parliamentary Standing Committee.

#### General Industry

**Publication: Mint**

**Edition: National**

**Date: November 19, 2013**

**Headline: [Policymakers, corporate leaders say India needs institutional reforms](#)**

**Synopsis:** India needs institutional reforms to improve its regulatory regime and has to go that extra mile to develop in-house technology and innovative processes to gain a competitive edge in manufacturing, which is struggling in the face of policy inaction and lack of technology advancement, according to policymakers and corporate leaders who participated in a Clarity Through Debate event organized on 30 October by Mint in partnership with Siemens AG's India unit. Participants included Arun Maira, member, Planning Commission; Rajat Kathuria, director and chief executive officer (CEO), Indian Council for Research on International Economic Relations (ICRIER); Dinesh Tyagi, CEO of CSC e-Governance Services India Ltd

**Publication: Business Standard**

**Edition: National**

**Date: 19.11.2013**

**Headline: [Ranbaxy is like a big ship, you can't change its direction overnight: Dinesh Thakur](#)**

**Synopsis:** Dinesh Thakur, who is now planning to start a new venture to help the industry and the US regulator avoid another Ranbaxy-like episode is still wary of disclosing his whereabouts for security reasons. In an interview with Sushmi Dey, he hopes Ranbaxy is a better company now under the new management.

**Publication: Pharmabiz**

**Edition: Online**

**Date: November 19, 2013**

**Headline: [Advanced pharma & allied machinery technology to boost Indian pharma industry](#)**

**Synopsis:** There is a lot of investment made by the pharma companies in India in latest technology for

improving the quality of medicines and making new variants of the product. This has been possible by the technologies accessible to the pharma industry from the tools given through pharma and allied machinery. Echoing his views on the occasion, Ajit Singh said that the success of such technologies is evident from the fact that our business accounts for 70 per cent of repeat orders from the clients. There are invisible costs also associated with the pharma process technologies which is attributed to the R&D projects successfully conducted by our group of 140 experts including designers, technologists and scientists. Citing the achievement of Dr Yusuf Hamid founder of Cipla in the development and pricing of AIDS medicine of high quality which led to saving of 10 million lives in Africa, Ajit Singh concluded, "We should take forward our commitment as being a front runner in manufacturing formulation products of standard global quality because pharma and allied machinery largely represents the solid dosage formulations segment. It has therefore been understood that with making generic production of high quality the pharma and allied machinery is dealing in very high technology to make affordable healthcare to the world."

**Publication: Pharmabiz**

**Edition: Online**

**Date: November 19, 2013**

**Headline: [CPhI India to be held in Mumbai from December 3 to 5](#)**

**Synopsis:** CPhI India, the international event dedicated to the chemical and pharma ingredient industry and organised by UBM, is slated to take place at the Bombay Exhibition Centre, between December 3 and 5, 2013. The event would see around 900 exhibitors and 28,000 visitors from 95 countries, including China, the United States, the United Kingdom, France and Italy. The event would be co-located with other events like CPhI, P-MEC, ICSE, BioPh and would also include conferences and seminars. As the pharma industry is increasingly looking towards India to source high-quality, low-cost pharma solutions, CPhI India 2013 would be the perfect platform for companies to pick up the latest trends and innovations the market has to offer.

#### Innovation

**Publication: Russia & India Report**

**Edition: National**

**Date: November 19, 2013**

**Headline: [Omsk business delegation offer India medical innovations](#)**

**Synopsis:** Several companies from Russia's Omsk region visited India with an export-oriented business mission showcasing hi-end medical research and diagnostic equipment and solutions and looking for business partners. Tarasyuk, who is leading the delegation, added that medicine and pharmaceuticals are the field where Russia and India have huge potential for cooperation. While India had reached significant results in developing of pharmaceutical industry, Russia had progressed in designing and production of innovative medical equipment.

#### OPPI

**Publication: The Economic Times**

**Edition: National**

**Date: November 18, 2013**

**Headline: [GlaxoSmithKline's CEO Andrew Witty backs India's pharma policy, cautious on acquisitions](#)**

**Synopsis:** Andrew Witty, chief executive officer of British drug firm GlaxoSmithKline, says he fully understands the Indian government's stance on issues such as pricing and patents, believing that these issues have to be looked at in the context of challenges that accompany rapid growth. Many multinational companies have severely criticised Indian authorities' stance on patents and the Organisation of Pharmaceutical Producers of India (OPPI) has strongly opposed pricing restrictions. NovartisBSE 0.83 %, one of the world's biggest drug companies, has said that it will not launch any new products in India and Pfizer has termed the country's policies anti-competitive. Witty's comments on pricing restrictions are interesting as GSK's pharma business, especially the sales of its important drug Augmentin, has been badly affected by the recent price cuts. In October, GSK India sales fell to 2,885 crore from 3,168 crore last year during the same month, data from the All

India Organisation of Chemists and Druggists (AIOCD) shows.

### Fire In The Blood

**Publication: The Hindu Business Line**

**Edition: National**

**Date: November 15, 2013**

**Headline: [‘Fire in the Blood’ set for debut in the corridors of power](#)**

**Synopsis:** Fire in the blood, a documentary that tells the story of “medicine, monopoly and malice”, is set to be watched by lawmakers across the world. Currently running in Indian cinemas, the internationally acclaimed film traces Africa’s struggle to access AIDS medicines about 10 years ago. The documentary tells its story through key players, including former US President Bill Clinton, economist Joseph Stiglitz, South African Nobel laureate Desmond Tutu and Indian drug-maker Cipla and its chief Y.K. Hamied. It highlights the difference Indian generic-drug companies make in Africa by providing access to affordable medicines — all thanks to their expertise in making cheap clones of innovative drugs. In India, the film will be made freely available on YouTube in about three months, said Gray. Globally, it will be freely available online in a year. The film-maker, who is married to Hamied’s niece, said civil-society groups are working to make screenings possible for more policy-makers. Smaller edits of the film are being sought for congressional and advocacy purposes. And since television brings in the biggest audience, the film is also ready for telecast in several countries, including Finland, Norway, Poland, Switzerland and Israel, in the next few weeks.

### Patents / Intellectual Property Rights / Compulsory Drug Licensing

**Publication: The Economic Times**

**Edition: National**

**Date: November 17, 2013**

**Headline: [Deal with Ranbaxy: Should Daiichi Sankyo have followed the Nemawashi way?](#)**

**Synopsis:** In 2008 Ranbaxy was at the cusp of something very big. Pfizer's atorvastatin brand Lipitor was approaching patent expiry. Atorvastatin is used for lowering blood cholesterol and had a \$11-billion market. Ranbaxy was the first to file for a generic in the US and would have had a period of exclusivity marketing the generic product. Pfizer and Ranbaxy were locked in legal battles across the world and there were offers from Pfizer itself and other pharma majors like GSK to buy out the Singhs from Ranbaxy. Last week, Daiichi Sankyo alleged that the Singhs did not fully disclose the details of the US FDA's investigations of the company's facilities that were on at the time of the takeover. In May Daiichi Sankyo had to pay a \$500-million fine in the US for violations at Ranbaxy's India operations. The company had paid \$4.9 billion for the Singh brothers' stake in the company and subsequent open offer and fund infusion.

**Publication: The Economic Times**

**Edition: National**

**Date: November 18, 2013**

**Headline: [Rajeev Kher taskforce mulls currency swap with Japan, South Korea to cut dollar outflow](#)**

**Synopsis:** India is exploring local currency trade with Japan and South Korea as it seeks to cut outflow of dollars, much needed to finance its large current account deficit. Delhi has a large trade deficit with both Japan and South Korea despite a bilateral comprehensive trade pact. The India-Japan comprehensive economic partnership agreement was concluded in 2011, whereas a similar one with South Korea was signed in 2009, which covers not only the goods and services trade but also areas like investment, competition policy, intellectual property rights and government procurement.

**Publication: The Financial Express**

**Edition: National**

**Date: November 18, 2013**

**Headline:** [IPAB rejects Swiss pharma giant plea](#)

**Synopsis:** The Intellectual Property Appellate Board (IPAB) has dismissed a review petition filed by Swiss pharma giant F Hoffmann-La Roche (Roche) and OSI Pharmaceuticals against an earlier IPAB order for receiving additional documents from Mylan Laboratories in a patent battle between the pharma companies, relating to Erlotinib hydrochloride, an active ingredient for anti-cancer drug Tarceva.

**Publication:** Business Standard

**Edition:** National

**Date:** November 16, 2013

**Headline:** [WikiLeaks expose: Drug makers see red](#)

**Synopsis:** The domestic drug manufacturing industry has raised concern at the revelations by the WikiLeaks anti-secrecy group, highlighting provisions proposed by the US government in the Trans Pacific Partnership (TPP) that could impact generic penetration into various countries. Patent experts, who have reviewed the document leaked by WikiLeaks, said provisions sought by the US attempt to block generic entry through intellectual property interventions. For instance, the proposal seeks to protect patents for brand name medicines in some participating countries and curtail access to low-cost generic drugs, experts said. The suggested provisions also attack section 3 (d) of the Indian patent law, which prevents patenting of incremental innovation. The Indian pharmaceutical industry, a major supplier of generics to the world, is worried that the US proposal poses a huge threat to its export revenue. According to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) data, around 60 per cent of the total pharmaceutical generics produced in India are exported, clocking annual revenue of \$14.7 billion. This is growing at 30 per cent yearly.

**Publication:** Business Standard

**Edition:** National

**Date:** November 18, 2013

**Headline:** [Markets to open higher tracking Asian peers](#)

**Synopsis:** Wockhardt would be in focus on reports that the Intellectual Property Appellate Board (IPAB) has directed the registrar of Trade Marks to cancel a trade mark registered by Gujarat-based Kamaron Laboratories Ltd, on a rectification application filed by Wockhardt Pvt Ltd, which claimed the mark was deceptively similar to its trade mark Zedex.

**Publication:** The Hindu

**Edition:** National

**Date:** November 15, 2013

**Headline:** [Developing countries call for easing IPR costs of clean technologies](#)

**Synopsis:** The issue of easing the costs of intellectual property resources on clean technologies takes centre stage. For the developed countries it was a devil buried at the climate negotiations last year at Doha. At the Warsaw talks, the developing countries, including India, resuscitated the devil — easing the costs of intellectual property rights (IPR) on clean technologies — back to life, by demanding that a funding mechanism be set up to buy licenses on clean but costly technologies to provide to the poor countries. The topic of intellectual property rights has been such a hot potato for the developed countries that at the climate talks last year, developing countries had to agree to back-burner it in order to build consensus.

**Publication:** The Hindu

**Edition:** National

**Date:** November 15, 2013

**Author:** Op-Ed - Prabha Sridevan, a former Judge of the Madras High Court, was Chairman of the Intellectual Property Appellate Board, May 2011 - August 2013

**Headline:** [Whose tribunal is it anyway?](#)

**Synopsis:** The independence of specialist tribunals must be ensured. But this is not happening, as the functioning of the Intellectual Property Appellate Board shows. The Intellectual Property Appellate Board (IPAB) is an example. The High Court's jurisdiction over IP rights was transferred to it. Therefore, IPAB members must have the rank, capacity and status as nearly equivalent to that of a High Court judge. Disputes of such moment come before the IPAB that sometimes even if a case is adjourned there is an echo outside India. Recent cases concerning drugs such as Pegasys, Nexavar, and Combigan were avidly followed abroad, and commented upon and criticised. There is no other court or tribunal in India, including, I dare say, the Supreme Court, whose proceedings have trans-border tremors. When the IPAB removed a drug patent, one side cried with despair as if Doomsday was upon us, and the other side cheered as if "Fiat Sanitas" had been pronounced. The truth is simply that the invention in question was found to be unworthy of a patent under Indian law. IP litigation has a strong public interest component, and decisions could affect the lives of millions. In every dispute, the interest of the unseen public is impacted in a seemingly adversarial litigation. This is so whether the dispute is over trademarks, patents or geographical indications — the three IP rights under the IPAB's jurisdiction.

**Publication:** Business World

**Edition:** National

**Date:** November 15, 2013

**Headline:** [Healthcare Hope](#)

**Synopsis:** On April 1st, the Supreme Court pronounced judgement in the long awaited Novartis AG v Union of India [Air 2013 SC 1311]. Recall that in 1997, Novartis filed a patent application for the cancer prescription drug Glivec claiming that it had invented the beta crystalline salt form of the freebase salt Imatinib. Based on this filing, on March 27th, 2002, it asked for and received Exclusive Marketing Rights under Section 24A the Patent Act (as it then stood) and then went about preventing generic manufacturers from selling unbranded versions of the same medicine. To get things in perspective, generic medicines offered this product at \$ 177-266 per patient per month while Novartis offered the same product at \$2666 per patient per month. Those who objected to the grant of patent basically argued that the Mesylate salt form of Imatinib was already in the public domain in 1997 and Novartis could not now ask to patent it. Novartis argued that the beta crystalline salt form it was seeking to patent was a huge improvement over the earlier known form: it showed a 30% increase in availability

**Publication:** Zee News

**Edition:** National

**Date:** November 15, 2013

**Headline:** ['India-EU trade deal unlikely in FY 2013-14'](#)

**Synopsis:** A free trade deal between India and the European Union is unlikely before the 2014 general elections as the current government won't be willing to make any unpopular compromises required to conclude the agreement, says a top diplomat from the grouping. The progress on the talks is stalled due to disagreements on the issues like import duties on automobiles, pharma and alcoholic products, and trade in services and intellectual property rights.

## Drug Pricing

**Publication:** The Economic Times

**Edition:** National

**Date:** November 18, 2013

**Headline:** [Glenmark Pharma: Export & domestic businesses on a strong footing](#)

**Synopsis:** The new drug pricing policy is not likely to have a big impact on the company. However, depreciation is likely to remain on the higher side in the near term. The company's elevated level of debt is a bit of a

concern. Analysts remain positive on the stock as the company is placed well to benefit from both its export and domestic businesses.

**Publication: The Times of India**

**Edition: National**

**Date: November 18, 2013**

**Headline: [Specialised E-retailers draw investor attention](#)**

**Synopsis:** Online retailers that sell only a single category of products are fast gaining investor attention as they require lesser capital to grow than multi-brand portals. Termed as vertical ecommerce portals, these ventures which sell specialised products for healthcare — ranging from prescription drugs to nutritional supplements and spectacles, baby care products and jewellery—cater to customers who buy high-value products at frequent intervals. The higher margins earned by these companies is making them attractive for investors who have put in a total of about Rs 664 crore so far this year. "We aim to build a valuable company that meets the investors' strategy of backing sustainable ventures," said Prashant Tandon, founder of Healthkart.

#### FDI

**Publication: The Economic Times**

**Edition: National**

**Date: November 18, 2013**

**Headline: [India Inc strikes 360 private equity deals worth \\$8.9 billion in January-October](#)**

**Synopsis:** Indian companies signed as many as 360 private equity deals totaling \$8.9 billion in the January-October period of this year, registering an increase of 33 per cent over the corresponding period a year ago. Others major deals that make up the top five deals in October include Warburg Pincus' 30 per cent stake acquisition in Biba Apparels for \$56.45 million and Actis \$48 million investment in Symbiotec Pharmed. A sector wise analysis shows IT and ITeS space cornered 34 per cent of the total deals as the sector saw 18 deals worth \$281 million, followed by pharma, healthcare (26 per cent with \$216 million), real estate (22 per cent, \$177 million), retail (7 per cent, \$56 million) and media and entertainment (4 per cent, \$30 million), the report said.

#### FDA / Drug Regulatory / DCGI

**Publication: Mint**

**Edition: National**

**Date: November 15, 2013**

**Headline: [UTI AMC will be more on the front foot: Leo Puri](#)**

**Synopsis:** For over two years India's oldest fund house, the erstwhile monopoly UTI Asset Management Co. Ltd did not have a leader. A two-year controversial search later, Leo Puri took over as the managing director of the asset management company in August. He said "In a country as immature as ours, in terms of financial deepening, the risk of regulatory overreach is high and we have to be very careful not to act prematurely. It is more like saying if you increase the cost of compliance and only offer a fully branded drug as opposed to a generic version of it, you are going to have a smaller market. I think you can add costs to a patent-protected regime which are perfectly justifiable but which will prevent you from reaching hordes of customers. There is an element to the regulation which is essentially more analogous to a patent-protected drug distribution regime. You cannot compromise on treating customers fairly but we have to be careful not to import definitions of what that means which are just too expensive or require a level of skill and sophistication among manufacturers and distributors which just don't exist in our country."

**Publication: Business Standard**

**Edition: National**

**Date: November 18, 2013**

**Headline:** [US FDA for greater freedom to generic companies](#)

**Synopsis:** US drug regulator FDA is planning to allow generic-drug makers, including those from India, to independently update product labelling when they discover new safety data, a move which can bring them at par with branded medicine manufacturers. Generic manufacturers, which make cheaper but therapeutically equivalent versions of innovative drugs, would be required to inform the brand name manufacturer about the labelling change. While the proposed rule raises public health policy questions like impact on generic drug cost, a section of generic companies are of the view that the new policy can open them up to failure-to-warn suits.

**Publication:** Business Standard

**Edition:** National

**Date:** November 18, 2013

**Headline:** [Ranbaxy looks to sell India-made generic medicines in Japan](#)

**Synopsis:** Ranbaxy Laboratories, the global generic arm of Japan's second-largest pharmaceutical company, Daiichi Sankyo, plans to supply medicines to the Land of the Rising Sun from its Indian facilities, according to sources. Though Ranbaxy is yet to get approvals from the Japanese regulatory agency, it is trying to get a foothold in that market to boost its consolidated revenues, sources added.

**Publication:** NDTV Profit

**Edition:** National

**Date:** November 17, 2013

**Headline:** [Singh brothers count on disclosure to counter Daiichi claims: report](#)

**Synopsis:** Facing arbitration claims here by Daiichi Sankyo, Ranbaxy's former Indian promoters are counting on 'representations and warranties' made in the share purchase agreement signed with the Indian drugmaker's current Japanese owners in 2008. At that time, Daiichi had said it "believes certain former shareholders of Ranbaxy concealed and misrepresented critical information concerning the US Department of Justice and the FDA investigations. Currently, Daiichi Sankyo is pursuing available legal remedies and cannot comment further on the subject at this time."

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 18, 2013

**Headline:** [Mfg licenses of several cos in Pondicherry may be revoked soon for violation of 122 E of D&C Rules](#)

**Synopsis:** The Pondicherry government may soon start revoking the drug manufacturing licences of several drug companies for violation of provision of 122E of the Drugs & Cosmetics Rules, it is learnt. The action is taken following the companies' alleged nexus with a corrupt regulatory officer who is now under suspension, a senior officer in the drugs control department informed Pharmabiz. J Jayaseelan, secretary of IPA Tamil Nadu and Pondicherry responded that the situation in the union territory was very critical.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 18, 2013

**Headline:** [Health Min to consult Commerce, Pharma depts on continued permitting of BA/BE studies for export purpose](#)

**Synopsis:** The Union health ministry will consult with all stakeholders including the Ministry of Commerce and the Department of Pharmaceuticals before taking a final call on whether to allow bioavailability/bioequivalence studies of drugs, discovered abroad and not marketed India, for export purpose

only. While considering the recommendation by the Prof Ranjit Roy Chaudhury expert committee in this regard, the health ministry is learnt to have decided to hold more consultations with all stakeholders on continued permitting of BA/BE studies for generating data for submission to foreign regulatory authority for export purpose.

#### Clinical Research / Trials

**Publication: Deccan Chronicle**

**Edition: National**

**Date: November 18, 2013**

**Headline: [Centre for filming clinical trials](#)**

**Synopsis:** The Union health ministry has proposed mandatory audio-visual recording of participants in clinical trials, making it tougher for drug companies to shrink responsibility when testing of their medicine reacts adversely on patients. Significantly, the new recommendations by a panel headed by Medical Council Of India (MCI) member Prof Ranjit Roy Chaudhury, the investigator can be debarred from clinical trials in case a violation is witnessed on their part. According to the new rules, in circumstances where informed consent has to be obtained from people with diminished capacity, the consent given by the guardian should be witnessed by an independent person who also has to sign the informed consent document.

**Publication: The Free Press Journal - Indore**

**Edition: National**

**Date: November 18, 2013**

**Headline: [Drug trials dominate talk show](#)**

**Synopsis:** State Health Minister and BJP candidate from Indore- 5 Mahendra Hardia and his rival and Congress candidate Pankaj Sanghvi attended the 'Face- To- Face' programme, organised by Indore Press Club, on Saturday. Sanghvi raised the issue of drug trials and said that 81 people died because of illegal drug trials conducted on 3300 people. " MoUs were signed during the Investor Summit but Hardia should tell the people which company has come to the city.

#### General Industry

**Publication: The Economic Times**

**Edition: National**

**Date: November 18, 2013**

**Headline: [Healthcare Costs may Result in Financial Ailment for Many Indians](#)**

**Synopsis:** Medical costs are on their way to becoming the number one personal finance crisis for more and more Indians. Anyone who keeps up at all with news knows that the US government shut down last month and somehow, some kind of health insurance reform measure called Obamacare had a role to play in it. In the developed world, the US is said to have the highest healthcare cost, the worst quality of healthcare and apparently, a health insurance system that is pretty hostile to its customers. Healthcare costs and health insurance have rapidly become a major financial concern of almost everyone, but the richest Indians. Government-provided healthcare basically works only for current and retired government employees.

**Publication: The Hindu Business Line**

**Edition: National**

**Date: November 17, 2013**

**Author: Anil Rajput, Chairman of the FICCI Committee against Smuggling and Counterfeiting Activities  
Destroying the Economy**

**Headline: [Just too few Indian brands](#)**

**Synopsis:** The Indian pharmaceuticals industry has been a success story in brand creation. Sun Pharma, Dr

Reddy's, Ranbaxy and Cadila are well known. Today, the pharma industry is growing at a healthy rate of 10 per cent per year. In 1986, the government established the Department of Biotechnology, under the Ministry of Science and Technology. The government provided tax incentives and grants for biotech start-ups and firms seeking to expand, along with establishing biotech parks.

All these steps helped both the Indian IT and pharma sectors emerge as shining examples of indigenous brand creation. The pharma sector too responded to the initiatives of the government.

**Publication: Business Standard**

**Edition: National**

**Date: November 18, 2013**

**Author: Op-Ed - Asish K Bhattacharyya, Professor and Head, School of Corporate Governance and Public Policy, Indian Institute of Corporate Affairs; Advisor (Advanced Studies), Institute of Cost Accountants of India; Chairman, Riverside Management Academy Private Limited**

**Headline: [CSR issues continue to remain unresolved](#)**

**Synopsis:** The Draft Rules state, "CSR projects/programmes of a company may also focus on integrating business models with social and environmental priorities and processes in order to create shared value." Michel Porter, the Harvard Professor, who introduced the term 'shared value' in a HBR (January-February 2011) article defines shared value as, "policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates." The Draft Rules state, "CSR Policy would specify that the corpus would include the following: 2% of the average net profits; any income arising therefrom; and surplus arising out of CSR activities."

**Publication: Daily News and Analysis**

**Edition: National**

**Date: November 17, 2013**

**Headline: [Needed: Overhaul of the healthcare system](#)**

**Synopsis:** The absence of adequate regulatory controls, treatment guidelines, and patient awareness has led to a huge global surge in antibiotic resistance. The problem is compounded by a desperate shortage of new drugs to treat multi-drug resistant bacterial infections, says a team of 26 medical professionals, including two from India.

**Publication: Financial Chronicle**

**Edition: National**

**Date: November 17, 2013**

**Author: G S Sundararajan, Op-Ed - Group director of Shriram Group**

**Headline: [MSMEs: Overbanked, yet underserved](#)**

**Synopsis:** India today needs financiers who would focus on a few sectors and MSMEs therein, rather than laying themselves threadbare! Time has come for specialist financiers for pharma, textile or food and beverages MSMEs in the manufacturing side or even agri-allied, auto-allied or retail oriented MSMEs.

**Publication: Pharmabiz**

**Edition: Online**

**Date: November 18, 2013**

**Headline: [Industry seeks customs relief on several items including life saving drugs & devices](#)**

**Synopsis:** The pharmaceutical industry in the country has urged the Union finance ministry to provide customs relief to the pharmaceutical exporters in the country on several items including all life saving drugs and all life saving medical devices. All life saving drugs and life saving medical devices should be exempted from customs duty. Besides, basic customs duty on formulations and other medical devices should be reduced to five per

cent. Import of all capital goods, raw materials, consumables, and reference standards for R&D purposes should be fully exempted from customs duty and others related duties, the industry in its pre-budget proposal to the finance ministry said.

## Innovation

**Publication:** The Economic Times

**Edition:** National

**Date:** November 18, 2013

**Headline:** [Impasse in Warsaw climate talks as developing nations stay united](#)

**Synopsis:** A senior negotiator from the Like Minded Developing Countries group, which includes India, China, Philippines, Venezuela, Saudi Arabia among others, said, "There are many measures that industrialised countries can take that would address the issue of increasing efforts to address climate change over the next seven years. They could for instance set up a window under the Green Climate Fund for funding intellectual property rights that would help developing countries access technology, reward innovation and not burden developing countries."

**Publication:** The Hindu

**Edition:** National

**Date:** November 18, 2013

**Headline:** ['Re-engineer healthcare to develop antibiotic resistance'](#)

**Synopsis:** Lack of adequate regulatory controls, treatment guidelines and patient awareness has led to a global surge in antibiotic resistance. The entire structure of healthcare delivery for effective antibiotics – from research and development, to distribution and rational use – needs to be re-engineered to address the looming global threat of antibiotic resistance, say the authors of a new report, published in The Lancet Infectious Diseases, ahead of European Antibiotic Awareness Day.

**Publication:** Pharmabiz

**Edition:** Online

**Date:** November 14, 2013

**Headline:** [Cadila Pharmaceuticals signs licensing deal with UK based Helperby Therapeutics](#)

**Synopsis:** Cadila Pharmaceuticals Limited, one of India's largest privately held pharmaceuticals company and UK based antibiotics discovery major, Helperby Therapeutics have signed a joint agreement on antibiotic drug resistance research & development. Described as the most important innovation in the discovery of new antibiotics since Alexander Fleming's original breakthrough more than 80 years ago, this announcement is a major breakthrough in the fight against resistance with the discovery of patented 'resistance breaker' compounds.