**Clinical Research / Trials**

**Publication: Business Standard** *(Reproduced from PTI)*  
**Edition: National**  
**Date: November 6, 2013**  
**Headline: Digvijay demands probe into drug trials in Madhya Pradesh**

**Synopsis:** Alleging a "huge scandal" over drug trials in government medical colleges in poll-bound Madhya Pradesh, Congress General Secretary Digvijay Singh today demanded a central government inquiry into the matter, claiming that more than 100 persons have lost their lives. In a letter to Health Minister Ghulam Nabi Azad, Singh, who is a two-time Chief Minister of Madhya Pradesh, accused the state government of "protecting" the doctors involved in the scam. "....A huge scandal has taken place in government medical colleges of Madhya Pradesh, where unsuspecting patients were made to undergo drug trials in which more than 100 people have lost their lives," Singh said in the letter. Singh had a few months back also demanded a probe by CBI into "illegal" clinical trials of drugs in Madhya Pradesh. According to NGOs and some doctors, illegal and unethical clinical trials were conducted on poor persons including juveniles, tribals and Dalits who were used as "guinea pigs" for testing of drugs and vaccines produced by multinational corporations.

**Publication: Pharmabiz**  
**Edition: Online**  
**Date: November 6, 2013**  
**Journalist: Joseph Alexander**  
**Headline: Health Min still to examine recommendations of Prof Ranjit Roy panel**

**Synopsis:** The recommendations of the expert committee, headed by Prof Ranjit Roy Chaudhury to formulate policies and guidelines on approval of clinical trials and new drugs, are still under the consideration of the Union Health Ministry and no final decision has been taken yet, it is learnt. The Ministry is learnt to be still examining the main suggestions of the report, submitted to the Ministry on August 8, 2013, even though the Government had submitted before the Supreme Court that recommendations would be considered for further streamlining the clinical trials sector. The Supreme Court is also expected to consider the suggestions from various stakeholders like the National Human Rights Commission, SAMA Resource Group for Women and Health & Low cost Standard Therapeutics and Indian Society for Clinical Research, apart from the views of petitioner and the Central Government on the matter. Meanwhile, the court had also allowed the petition by Indian Pharmaceutical Alliance seeking to intervene in the present case. The case was filed in February, 2012 by the NGO alleging that Indians were being made victims of unregulated clinical trials.

**Publication: Pharmabiz**  
**Edition: Online**  
**Date: November 6, 2013**  
**Journalist: Ramesh Shankar**  
**Headline: Health ministry fails to make BA/BE studies mandatory after 2 years of proposing**

**Synopsis:** Even after more than two years since it approved the proposal, the union health ministry's effort to make registration of bioavailability and bioequivalence (BA/BE) studies mandatory with the Clinical Trial Registry of India (CTRI) is still stuck in the bureaucratic red-tapism, thanks to the bickering between the two departments under the ministry over providing the required funds for the scheme. According to sources in the National Institute of Medical Statistics (NIMS), which has been given the responsibility to make the necessary changes in its web network to incorporate the BA/BE features, the drugs controller general of India (DCGI)'s office (CDSCO) and the Indian Council
of Medical Research (ICMR), both coming under the ministry of health, are passing the buck on the issue of providing the required funds for the project.

Synopsis: Rajiv Gandhi Cancer Institute, Delhi is organising a one-day conference on ‘Adapting to the Current Regulatory Challenges in conduct of Clinical Research – Focus on Sites and Ethics Committees’ on November 9, 2013 at Amaltas Hall, India Habitat Centre, Delhi. The main aim is to upgrade the knowledge of clinical research professionals on current challenges in clinical research conduct and to brainstorm and network with fellow professionals to learn from each other. The event is co-organised by Auriga Research Ltd. & SenseCR and supported by Pfizer Preferred Research Centre (PRC), RGCI. Dr D C Doval, chief of medical oncology and director (Research) and Shilpa Garg Agrawal, founder & CEO, SenseCR will be inaugurating this event and A K Pradhan, Deputy Drug Controller India, CDSCO, will be the chief guest for the event. Pradhan will address on impact of current regulatory changes on clinical research conduct for sites.

Synopsis: The Planning Commission has opposed a proposal by the Department of Industrial Policy & Promotion (DIPP) to limit foreign direct investment (FDI) in companies making ‘critical drugs’ to 49%, saying it entails a complete reversal of the existing policy that allows 100% FDI in the sector. Without imposing a cap on FDI, the government has already tightened the rules to put in place some conditions and ensure that such investment in existing pharmaceuticals companies require government approval. This followed much debate within the government on rising foreign investments in the sector and takeover of some big India drug manufacturers amid fears that multinationalisation of India's successful pharma industry would deny cheap drugs to local consumers. The finance ministry has also strongly opposed DIPP's proposal requiring the backing of department of health and science and technology. The Planning Commission has said the evidence to revisit the pharma FDI policy in effect from 2011 is not satisfactory.

Synopsis: Decision to change FDI policy in pharma sector has been quite a bone of contention between health, commerce & industry and finance ministries. The Cabinet Committee on Economic Affairs (CCEA) is likely to consider a proposal seeking changes in the foreign direct investment (FDI) policy for pharmaceutical and real estate sectors in its meeting on Thursday. While both the health ministry and the commerce ministry have batted for putting more restrictions for new players entering the pharma sector here, the finance ministry does not want any riders that would hit foreign exchange earnings. Commerce and industry minister Anand Sharma has maintained that the new policy will make sure effective safeguards are put in place and monitored, keeping in mind the concerns over a series of takeovers of domestic pharmaceutical companies by international players.
Synopsis: According to the Constitution, pharmaceuticals, like electricity, are a concurrent subject. The central government makes the rules on matters that affect more than one state while state governments draft rules for matters within their respective states. For the pharma sector, these include rules on manufacturing, retail, and preventing sub-standard drugs from reaching the consumer. Similarly, electricity is under the central government on interstate matters (like interstate transmission rules, the grid code, etc). State governments make the rules for generating plants within the state and for intra-state transmission and distribution. There are state load dispatch centres that supervise the operations of the grid within the state. Drug controllers in each state supervise the pharmaceutical manufacture and trade in the state. Both load dispatch centres and state drug controllers are under the overall control of the respective ministries in the state government. Thus, the state drug controllers are under the secretary in the health ministry, and like heads of load dispatch centres, much lower in the hierarchy.

Coordination between the Centre and the states is vital. Electricity follows no political boundaries but flows along the wires taking the path of least resistance. Similarly, drugs are traded all over the country, irrespective of where they are made.

Synopsis: India’s patenting criteria receive both global censure as well as appreciation for their exclusion of incremental inventions of little curative value. But the country doesn’t appear too stingy in granting these exclusive rights. A cursory look at the database reveals little difference between Big Pharma and homegrown companies on their patent strategies, after the country embraced product patenting in the pharmaceutical sector in 2005. Of course, some like Swiss major Novartis appear to have been less choosy than others when it comes to patent filings in India, while a few others — notably US major Pfizer — have recorded much better success rates in securing patents in India due to their selective approach. The Indian government claims that Section 3(d) is compliant with the WTO’s Trade Related Aspects of Intellectual Property Rights (TRIPS), a view more or less endorsed by the World Intellectual Property Organisation (WIPO).

Synopsis: Keryx Biopharmaceuticals Inc's kidney drug proved effective in treating chronic kidney disease patients not on dialysis, sending the company's shares to a seven-year high on hopes the drug could achieve blockbuster status. Sanofi SA, which markets two similar drugs that will lose patent protection next year, could partner with Keryx to develop or market Zerenex, Kolbert said. Sanofi's Renvela and Renagel are considered standard treatments to reduce phosphorus levels in kidney disease patients on dialysis.
Synopsis: While, govt is still in the process of fully implementing new prices fixed for 348 essential medicines, it has realised that most of these are no longer in supply. The National List of Essential Medicines (NLEM) — which took a little more than eight years for the government to finalise and another couple of years for the prices to be regulated — could be revised soon. While the government is still in the process of fully implementing the new prices fixed for 348 essential medicines, it has realised that most of these are no longer in supply. This is because companies have already started manufacturing many of these drugs with either special delivery mechanism (an improved and fast acting version of the basic formulation) or in combination with other ingredients, circumventing price control. According to an official, the National Pharmaceutical Pricing Authority (NPPA) has written to the department of pharmaceuticals (DoP), seeking its advice. Following NPPA’s letter, the department is considering floating a proposal to revise the NLEM and has also referred the matter to the health ministry. The list was originally prepared by the health ministry, following directions from the apex court. While the new Drugs Price Control Order (DPCO) came into effect in May bringing 652 packs of 348 essential medicines under price control, NPPA has so far been able to notify prices of merely 338 packs, about half the total. There are provisions for periodical update of NLEM and if the government decides to do it now, the exercise will take some time as it is a long-drawn process. Besides, it may impact the industry only if the DoP takes a view that the list has to be brought under price control, says Indian Pharmaceutical Alliance (IPA) Secretary General DG Shah.

Publication: Business Standard (Reproduced from PTI)
Edition: National
Date: November 5, 2013
Headline: No right more fundamental than right to health: NHRC Chairman
Synopsis: Expressing concern over the limited reach of public health services and the high cost of private treatment in the country, National Human Rights Commission Chairman, Justice (retd) KG Balakrishnan, today said no right is more fundamental than the right to health. Limited reach of the public health system and high cost of private treatment are points of concern. The progress in the health sector is very slow, impacted by a shortage of doctors, paramedical staff and ethical issues related to clinical drug trials, drug pricing and unnecessary surgeries, Balakrishnan said. Inaugurating a two-day national conference here on 'Health Care as a Human Right', he said that the success of a public health system lay in easy accessibility, availability and affordability of treatment.

Publication: The Economic Times
Edition: National
Date: November 6, 2013
Headline: Japan's Eisai to launch breast cancer drug in India
Synopsis: The $7-billion Japanese pharmaceutical company Eisai, which set up operations in India nearly eight years ago, is extending its affordable pricing strategy by introducing a critical breast cancer drug through a tiered model. Priced at about 31,000 per vial, Eisai will experiment with differential pricing within India. The exorbitantly-priced drug Halaven, which costs around Rs 4.8 lakh per four cycles, prescribed as a third-line treatment for metastatic breast cancer, will be offered to those from lower socio-economic classes free of cost. This is in addition to the two other medicines already sold under the affordable pricing strategy at one-tenth of the global price, says the company’s Asia deputy president Yuji Matsue. Innovative drugs, anti-Alzheimer's drug Aricep and gastro-intestinal drug Parit, are already sold under an affordable pricing strategy here. Eisai’s move comes at a time when multinational companies have threatened not to introduce any new products in India because of what they term as an unfriendly intellectual policy regime.

Publication: Bloomberg BusinessWeek
Edition: Online
Date: November 6, 2013
Headline: Glaxo to Lupin Fight Traders to Revive Margins: Corporate India
Drugmakers from GlaxoSmithKline Plc (GSK) to Lupin Ltd. (LPC) are grappling with Indian distributors, whose demand for maintaining commissions threatens to erode profits after the South Asian nation imposed price controls. Talks are under way after traders temporarily boycotted some treatments until their demands were met, Nilesh Gupta, managing director of Lupin, a maker of anti-tuberculosis medicines, said in an interview. Distributors want the terms of their commission to be restored after drugmakers slashed margins for traders following India’s move to cap prices of 348 essential remedies.

Publication: Financial Chronicle
Edition: National
Date: November 5, 2013
Journalist: Soumonty Kanungo
Headline: Despite ban, UK watchdog at ease with Wockhardt drugs

The troubled drug maker, Wockhardt, which came under strict scrutiny by two international drug regulators, has got a breather, thanks to its less expensive drugs supplied to the US, the UK and Europe that cannot be easily copied by companies in these markets. Though the two foreign regulators withdrew their earlier approvals for Wockhardt’s various plants, they allowed certain prescription drugs and essential drugs to be manufactured and supplied to their markets, citing supply constraints and absence of other manufacturers of these medicines. But industry officials and analysts say their decisions stem from the fact that the prices of similar drugs supplied by local players are several times higher, and that a complete ban on Wockhardt drugs could harm their domestic market. In a recent move, the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) issued a restricted good manufacturing practices (GMPs) certification to Wockhardt’s Chikalthana unit (in Aurangabad).

Publication: Reuters India
Edition: Online
Date: November 6, 2013
Headline: Drug pricing challenges diabetes king Novo Nordisk

Drug pricing is emerging as a key challenge for Novo Nordisk, the world’s biggest insulin producer, whose previously unstoppable growth has started to flag, according to the Danish firm’s chief executive.

Publication: Pharmabiz
Edition: Online
Date: November 6, 2013
Headline: NPPA’s expert panel yet to recommend retail prices of new drugs on principles of ‘pharmacoeconomics’

With the expert panel appointed by the National Pharmaceutical Pricing Authority (NPPA) failing to recommend the retail prices of new drugs on the principles of ‘pharmacoeconomics’ under the new Drug Price Control Order, (DPCO) 2013, the price regulator has sought the help from the industry to scout for agencies that will take up the task. According to the new DPCO, the NPPA was to appoint a standing committee for fixation of retail prices of new drugs for existing manufacturers of scheduled formulations. “The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of ‘pharmacoeconomics’,” the order said.

Publication: Pharma Times
Edition: Online
Date: November 6, 2013
Headline: New UK drug pricing details expected tomorrow

Long-awaited details of the new drug pricing landscape in the UK are to be announced tomorrow (Wednesday), PharmaTimes World News has learned.
There has been much debate over what shape the new system will take ever since the planned introduction of value-based pricing (VBP) in 2014 was announced by the government, and details remain sketchy. What is known is that the National Institute for Health and Care Excellence (NICE) will be responsible for assessing the price of new drugs under the National Health Service, taking into account variables such as wider societal benefits and burden of illness. The idea is to better to link the price of a newly-approved drug to its value, and thus, according to the government, improve outcomes for patients through better access to effective medicines, stimulate innovation and the development of high value treatments, better the process for assessing new medicines, and ensure value for money for the NHS.

**Fire in the Blood**

**Publication:** The Hindu Business Line  
**Edition:** National  
**Date:** November 4, 2013  
**Author:** Kajal Bharadwaj (Lawyer working on HIV, health and human rights)  
**Headline:** AIDS, the real story

**Synopsis:** The film, Fire in the Blood, released earlier this year and the toast of Sundance (a festival for documentaries) is finally being screened in India. It tells the powerful story of activists, doctors and journalists who fought to bring generic AIDS medicines to developing countries; the pharmaceutical industry and Western governments that tried to stop them; and the millions who died waiting for those medicines. The film comes barely a year after the Oscar-nominated How to Survive a Plague documented the struggle of AIDS activists in the US who successfully challenged the political, scientific and medical establishment to identify a treatment for HIV in the 1980s and 1990s.

**Publication:** Bolly Spice  
**Edition:** Online  
**Date:** November 2, 2013  
**Headline:** Indian Documentary Fire in the Blood Breaks record for longest run in Indian cinemas

**Synopsis:** Sundance Grand Jury Prize-nominated Indian film Fire in the Blood has been held over for a fourth week at PVR Phoenix in Mumbai, thus becoming the first-ever nonfiction film to achieve a four-week commercial theatrical run in India. Fire in the Blood tells the story of a unique and eclectic group of people who came together from India and other parts of the world to stop the ‘Crime of the Century’, whereby low-cost AIDS medicine was being deliberately withheld by Western pharmaceutical companies and governments from reaching Africa and other parts of the developing world, resulting in a minimum of ten million needless deaths.

**Clinical Research / Trials**

**Publication:** Business Standard  
**Edition:** National  
**Date:** November 1, 2013  
**Headline:** Malignant growth

**Synopsis:** The rot in the Indian pharma sector has spread across all levels - from clinical trials to manufacturing, prescription and retail. Last week, while Narendra Modi yet again contorted facts, Rahul Gandhi bared his family’s heart of gold and Prime Minister Manmohan Singh stuck to not-so-masterly inactivity, the country’s pharmaceutical sector grappled with three serious developments. One, a Supreme Court directive brought to a halt 157 clinical trials going on in the country. Two, the United Kingdom’s health regulator withdrew the good manufacturing practice certification for the Kadaiya (Daman) factory of Wockhardt. This was the fourth instance of the homegrown drug maker facing regulatory heat from abroad, and the umpteenth allegation of substandard Indian manufacturing. And three, the Union ministry of chemicals and fertilisers had to call an urgent meeting of drug makers and retailers to resolve an impasse over trade margins which has caused scarcity of essential medicine in some pockets of the country. Clinical trials, manufacturing, prescription and retail - malpractices abound at every stage. India, considered for long an inexpensive destination for human clinical trials, lacks adequate laws to regulate these experiments.
conducted on vulnerable patients who often do not even properly know the disease they are suffering from. Instead, the law regulating clinical trials seems to allow the trial sponsors to get away without even a rap on the knuckles in case of death or adverse effects. According to the health and family welfare ministry, there were 2,868 deaths in clinical trials during 2005-2012; however, merely 89 of these were accepted as trial-related and 82 were compensated. Last year, 436 people died during clinical trials but only 16 of these deaths have been attributed directly to the trials. Compensation has been paid in only two of these cases: while Novartis gave Rs 2.5 lakh in one case, Sun Pharma made an interim payment of Rs 50,000 in the other.

Publication: The Hindu Business Line
Edition: National
Date: November 1, 2013
Headline: Pharma sector woes far from over, says CII-PwC report

Synopsis: A tough economic environment is not the only thing dogging the pharmaceutical sector – it also has to contend with regulatory uncertainties. A CII-PwC report, ‘Changing landscape of the Indian pharma industry’, notes that the industry’s growth has dropped to 9.8 per cent in 2013, from 16.6 per cent last year. The industry is valued at Rs 72,069 crore in 2013. In addition to the growth challenges, the pharmaceutical industry is currently grappling with a number of issues, like delays in clinical trial approvals, uncertainties over the FDI policy, the new pricing policy, a uniform code for sales and marketing practices and compulsory licensing, the report said.

Publication: Pharmabiz
Edition: Online
Date: November 4, 2013
Headline: US FDA norms on electronic source data in clinical investigations seen to ensure transparency & traceability

Synopsis: The US Food and Drugs Administration (FDA) has issued norms on guidance for Industry on the Electronic Source Data in Clinical Investigations. It has clearly defined its recommendations to sponsors, Contract Research Organizations (CROs), clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations. The eCRF is an auditable electronic record of information that generally is reported to the sponsor on each trial subject, according to a clinical investigation protocol. It enables clinical investigation data to be systematically captured, reviewed, managed, stored, analyzed, and reported said the regulator.

Publication: The Times of India
Edition: National
Date: November 3, 2013
Headline: Free sugar tests at medical stores likely in Rajasthan

Synopsis: These provisions have been mooted by the All India Organization of Chemists and Druggists (AIOCD) in a unique model of advance pharma shops, a retail plan, which is likely to boost the pharmaceutical industry at large. After Maharashtra, Rajasthan may be the second state to implement the plan as a pilot project. According to AIOCD president JS Shinde, the Centre has already opened gates for foreign direct investment (FDI) and therefore many big houses have already entered into retail pharma trade in Metro cities. International players are also looking to target the pharma trade in India which is estimated over Rs 50,000 crore. AIOCD has initiated the first pilot project in Maharashtra. It has arranged professional training programs to existing retailers and patient counseling courses (PCC) in upgrading their knowledge and skill. Every affiliated pharmacist is getting trained for minimum 16 days on technical and behavioral subjects to stand out for fair and best practices. These courses are conducted with guidance and cooperation of learned faculty members which includes eminent doctors, professors, industrialists and management personnel. Customers can expect high service level, maintenance of their medical history, free home delivery to geriatric patients, free health counseling, free initial diabetic tests, blood pressure monitoring tests, customer loyalty programs, prescription refill reminder services, and patient counseling. Pharma outlets to offer free
tests and health management services. Chemists to be trained on technical and behavioral subjects. Customers can expect high level of services. Uneducated will get complete and free health management advisory services.
have been challenging for the branded drug industry, given the magnitude of patent expiries during the period. While R&D budgets are usually the least desirable area for cutbacks, expense cutting has occurred as the industry responded to financial and operational pressures resulting from patent expiries.

**Publication:** The Hindu  
**Edition:** National  
**Date:** November 4, 2013  
**Headline:** Indian Ambassador to U.S. bids farewell

**Synopsis:** Nirupama Rao, India’s Ambassador to the U.S., marked the end of her tenure here as well as a forty-year career in diplomacy, at a function at the embassy residence attended by a galaxy of diplomats and well-wishers. As India’s U.S. Ambassador, she frequently travelled the breadth of the nation to connect with Americans and deepen people’s understanding of India. She also maintained strong personal relationships with members of the U.S. Congress, many of whom were in attendance at the residence. Ms. Rao was also a strong advocate of India’s views on numerous contentious issues in foreign policy, most recently including India’s position on patent law. In the face of strident voices criticising the Indian Supreme Court’s decision to deny pharmaceutical giant Novartis a patent for its cancer drug Glivec earlier this year, Ms. Rao wrote an op-ed in The Hill’s Congress blog where she firmly argued that India honours, not dishonours, patent laws. In the article she emphasised that India sought to ensure a fair balance between the interests of innovators and the urgent need for improved health care.

---

**Publication:** South Asia Mail  
**Edition:** National  
**Date:** November 4, 2013  
**Headline:** Asthma medicines still unaffordable for many

**Synopsis:** Globally around 300 million people suffer from asthma, yet for many of them living in low- and middle-income countries access to quality-assured, affordable asthma essential medicines still remains a distant dream. This was revealed in a study conducted by Dr Zaheer Babar from the School of Pharmacy at the University of Auckland and Dr Karen Bissell from the University’s School of Population Health and International Union Against Tuberculosis and Lung Disease (The Union), and published in the journal PharmacoEconomics. Procurement of generic medicines is generally expected to result in cost saving and improved affordability. In the majority of cases the prices for innovator brand medicines were found to be higher than for the generic medicines. But in India and Kenya the price of innovator brand salbutamol in private retail pharmacies was less than the generic medicine.