News Updates: October 25, 2013

Fire in the Blood

Publication: Hindustan Times
Edition: Online
Date: 25.10.2013
Headline: Lifting the veil off Big Pharma's dirty deeds

Synopsis: Irish-Punjabi filmmaker Dylan Mohan Gray says it's a modern-day "genocide" that has since 1996 caused 10 million deaths — more than the Holocaust — and yet isn't much talked or written about, says about the subject of his debut documentary Fire in the Blood that released in India on October 11. Perhaps, the reason this documentary might be most damning for Big Pharma is because it features Peter Rost, a former senior vice-president (marketing) at Pfizer, who had earlier served in senior management positions at two other drug companies, before turning whistleblower against business methods of the industry. "I have noticed that whenever he comes on screen, audiences are riveted," Gray says. "That's because he says things nobody else will."

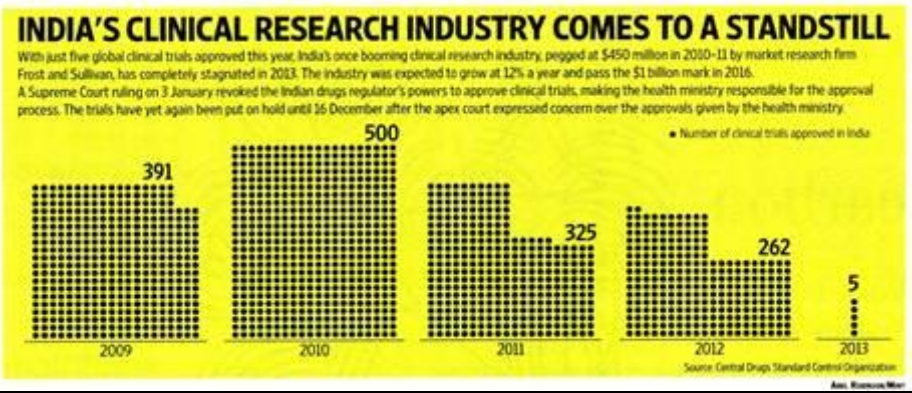
Publication: Daily News and Analysis *(Reproduced from IANS)*
Editions: National
Date: 25.10.2013
Headline: Documentary Fire In The Blood enjoys successful third week

Synopsis: The film is being currently screened as a part of the "PVR Director's Rare", an alternative programming initiative of PVR Cinemas to support the theatrical release of critically acclaimed, independent films. Thanks to an overwhelming response Indian documentary "Fire In The Blood" is enjoying a successful run in Mumbai.Now the plans are to screen the documentary in cities like Mangalore, Hyderabad and Chennai this week.

Clinical Trials

Publication: Mint
Editions: National
Date: 25.10.2013
Headline: India's Clinical Research Industry Comes To A Standstill *(No link available)*

Synopsis: With just five global clinical trials approved this year, India's once booming clinical research industry, pegged at $450 million in 2010-11 by market research firm Frost and Sullivan, has completely stagnated in 2013. The industry was expected to grow at 12% a year and pass the $1 billion mark in 2016. A Supreme Court ruling on 3 January revoked the Indian drugs regulator's powers to approve clinical trials, making the health ministry responsible for the approval process. The trials have yet again been put on hold until 16 December after the apex court expressed concern over the approvals given by the health ministry.



Publication: BusinessWorld
Editions: National
Date: 25.10.2013
Headline: How To Get Clinical Trial Industry Back On Track

Synopsis: Early this week, the Supreme Court raised serious concerns over the manner in which 162 clinical trials were approved by the health ministry until August 2013. The SC wanted 157 of these trial approvals to be re-examined by expert committees set up by the ministry to assess the risk-benefit ratio, innovations to existing therapeutic options and benefits to medical needs of the country. In the case of the remaining five, SC called for a freeze in the trials until the ministry put in place a proper mechanism to ensure the safety of the clinical trial volunteers. It has also asked for audio-visual documentation of the trial while maintaining its confidentiality.

Publication: Pharmabiz
Editions: Online
Date: 25.10.2013
Headline: India to assume leadership status in clinical trials once govt accepts & implements expert panel recommendations: Prof. Ranjit Roy

Synopsis: India will soon assume the leadership status in clinical trials and garner the limelight as the hub of global human studies once the government accepts and implements the expert committee recommendations on clinical trials, said Prof. Ranjit Roy Chaudhury who headed the committee which recommended sweeping changes in clinical trial sector in the country. The principal investigator of the trial should be an accredited clinical investigator. The ethics committee of the institute must also have been accredited. Only those trials conducted at centres meeting these stipulations will be accepted by the Drugs Controller General of India (DCGI).

Publication: Asian Human Rights Commission
Editions: Online
Date: 25.10.2013
Headline: INDIA: Supreme Court blasts the government for turning citizens into guinea pigs

Synopsis: It has been well aware of the unethical practices adopted by the private interests as evidenced by the outrage over the death of seven girls in post-licensure clinical trials conducted on tribal girls in Khammam in Andhra Pradesh and Vadodara in Gujarat in 2010. The trials, jointly conducted by the Indian Council of Medical Research (ICMR) and the state governments to test the efficacy of the human papillomavirus (HPV) vaccine, were suspended after the uproar. The inquiry committee formed to look into the issue found serious violations of the ICMR guidelines, mostly over consent related issues, and yet chose not to fix any criminal culpability of those responsible on the pretext that there was no deliberate or planned attempt to cause damage to persons taking part in the trials.

Publication: Mondaq
Editions: Online
Date: 25.10.2013
Headline: India: Food & Pharma Flash - October 2013

Synopsis: Ever since the clinical trials have come under the scanner of the Supreme Court of India ("SC") following its order on January 3, 2013, the regulatory agencies, the Drug Controller General of India ("DCGI") and the CDSCO have intensified the monitoring of the clinical trials and the government had also set up Apex Committee and Technical Committee to supervise the clinical trials. In the last few years, they have issued notices in 235 cases and inspected 577 clinical trial sites. Increased proactive steps and new guidelines have resulted in a sharp decline in the number of clinical trial approvals. Till the end of August this year, the DCGI has given permission to only 162 clinical trial applications.

FDA

Publication: The Economic Times
Editions: National
Date: 25.10.2013
Headline: Unichem gets USFDA nod for generic hypertension tablets

Synopsis: Unichem Laboratories today said it has received approval from the US health regulator USFDA for its generic amlodipine besylate tablets used for treating hypertension and coronary artery disease. The product in the strengths of 2.5 mg, 5 mg and 10 mg are equivalent to Pfizer Inc's Norvasc tablets in the same strengths, it added. The product in the strengths of 2.5 mg, 5 mg and 10 mg are equivalent to Pfizer Inc's Norvasc tablets in the same strengths, it added.

Publication: Business Standard
Editions: National
Date: 25.10.2013
Headline: Now USFDA gets a call from Indian pharma players

Synopsis: Indian industry body seeks dialogue to understand issues surrounding the industry and the concerns raised by the regulator. The domestic pharmaceutical manufacturing industry has initiated talks with the US Food & Drug Administration (FDA) following frequent enforcements from regulators around the globe. and the subsequent impact on sales. The US is the Indian pharmaceutical industry's largest revenue churning market.

Publication: Business Standard
Editions: National
Date: 25.10.2013
Headline: Pharmacies pushing sale of narcotics in Goa: probe

Synopsis: 'Medicinal narcotics' available on shelves are becoming an alternative to the traditional narcotics in Goa's coastal belt with several pharmacies allegedly pushing these scheduled drugs, a probe by Anti-Narcotics Cell has revealed. Police investigations, following recent seizure of Amphetamine, a scheduled drug allowed to be sold under the strict monitoring of Food and Drugs Administration (FDA), have revealed that some pharmacies allegedly have nexus with peddlers or end users, official sources said.

Publication: Reuters India
Editions: Online
Date: 25.10.2013
Headline: FDA recommends tightening access to hydrocodone pain-killers

Synopsis: The U.S. Food and Drug Administration on Thursday recommended tighter restrictions on products that contain hydrocodone, an opioid painkiller present in commonly prescribed, potentially addictive drugs such as Vicodin. Several companies, including Pfizer Inc and Endo Health Solutions, have been working to develop tamper resistant opioids that cannot be easily crushed or dissolved by addicts looking to get a full dose of the drug quickly.

FDI

Publication: Telegraph India
Editions: National
Date: 25.10.2013
Headline: Govt to stock up on dollars for a rainy day

Synopsis: The government and the Reserve Bank will try and build a war chest of dollars to protect the rupee before the US Federal Reserve starts tapering its stimulus policy next year. Bringing in NRI deposits and taking steps to ease foreign investment flows will feature high on their to-do list. Officials feel that a more liberal interpretation of FDI rules will be done to ease foreign fund flow. Mere fears that an acquisition in the pharma

sector will result in drugs being taken off the market will not be allowed to influence approvals, officials said.

Patents

Publication: Pharmabiz
Editions: Online
Date: 25.10.2013
Headline: GIPC urges India to strengthen IP laws to utilize its vast knowledge pool and create more jobs

Synopsis: The US Chamber of Commerce's Global Intellectual Property Centre (GIPC) has urged India to encourage innovation in the country and strengthen its Intellectual Property (IP) laws to utilize its vast knowledge pool and create more jobs**.** The Chamber, on behalf of the business community, had recently written to President Barack Obama, urging him to hold detailed discussions with the Indian Prime Minister Dr Manmohan Singh when the latter visited the US. In the recent study by GIPC, 'International Intellectual Property Index: Measuring Momentum', it was revealed that India ranked last in nearly all five indicators including patents, trademarks, copyrights, enforcement, and international treaty participations. Moreover, the country also has the lowest score on the pharmaceutical IP index due to significant gaps in the biopharmaceutical IP rights environment. On the surface, India appears to be a hotbed of clinical trials with its pool of facilities, trained research personnel, low costs of operation, and a large potential market but inadequate IPR laws have restricted clinical trials as well as research and development.

Publication: Pharmabiz
Editions: National
Date: 25.10.2013
Headline: Industry urges govt to extend 200% weighted deduction on R&D expenses for 5 years

Synopsis: The pharmaceutical industry in the country has urged the union finance ministry to concede several concessions on weighted deduction including the extension of weighted deduction of 200 per cent of research and development (R&D) expenses in an in-house facility for further period of five years. Pleading to allow weighted deduction on bio-equivalence (BE) studies conducted outside the R&D facilities, the industry apprised the government that pharma companies having their own approved R&D facilities have to get BE studies through outside agencies before they launch their products in the market. The industry also urged the finance ministry to extend the weighted deduction to expenditure on product registration in foreign countries and consultants' fees for patent/ product registrations overseas.

Publication: Pharmabiz
Editions: National
Date: 25.10.2013
Headline: Eli Lilly net income dips by 9.3% to $1,203 million in Q3

Synopsis: Dr John C Lechleiter, chairman, president and CEO, said, As we navigate through a period of expiring patents for some of our largest products, Lilly continues to deliver solid financial results and to advance our late-stage pipeline, with four regulatory filings completed this year alone. We are successfully executing our strategy which will enable us to return to growth after 2014 by bringing to the market new medicines that make a real difference for patients.

Drug Pricing

Publication: Business Standard
Editions: National
Date: 25.10.2013
Headline: Bhupesh Bhandari: Playing around with drugs

Synopsis: Unnecessary interventions bring about serious distortions in the marketplace. This is the basic principle of free markets and the efficient allocation of resources. Unfortunately, the United Progressive Alliance seems to be blissfully unaware of this. A good example of this can be seen in the drama being played out in the pharmaceutical market, thanks to the recent Drug Price Control Order, or DPCO 2013. It has fixed price caps on

348 medicines and 650 formulations.

General Industry

Publication: Business Standard
Editions: Online
Date: 25.10.2013
Headline: PM seeks Chinese investments in Indian infrastructure projects

Synopsis: Prime Manmohan Singh today sought Chinese investments in manufacturing and infrastructure sectors in India and called for market access in China for Indian IT and Pharmaceutical firms.

Publication: Pharmabiz
Editions: Online
Date: 25.10.2013
Headline: Madhya Pradesh fast catching up with Maharashtra and Gujarat in pharma manufacturing

Synopsis: Madhya Pradesh is fast catching up with neighbouring states like Maharashtra and Gujarat due to presence of pharmaceutical manufacturers such as IPCA Laboratories, Lupin, Cipla, Ranbaxy, Pentagon, Plethico, Alpa labs, MCW Healthcare, IMA-PG etc, according to Dr V G Somani, Joint Drugs Controller General (India). The Pharma Tech Expo 2013 proved to be a major specialized event where exhibitors showcased their latest advancements, achievements, modern technologies and newest trends within the industry in manufacturing, packaging, R&D etc for business generation and upgradation. It had projected quality controls and government regulations and controls. It also projected the brand value of organisations, joint venture firm, partnership firm, project collaborations, transfer of technology, investments and R&D.