News Updates: October 26-28, 2013

Fire in the Blood

Publication: The Times of India
Editions: National
Date: 27.10.2013
Headline: Thinking man's party

Synopsis: Bunty Chand, executive director of Asia Society India Centre says at our programmes, knowledge can be absorbed in a much deeper way, be it through a set of powerfully elucidated facts, a passionately argued perspective, or a poignant film like the documentary Fire in The Blood, which investigates public access to affordable medicine. In many ways, the proliferation of traditional and social media has led to an information overload. Organizations like ours are important to separate the news from the noise.

Publication: Bolly Spice
Editions: National
Date: 27.10.2013
Headline: Sundance nominated Indian documentary 'Fire In The Blood' now in its 3rd successful week at theatres

Synopsis: Due to overwhelming public response and strong critical acclaim, Sundance nominated, award-winning Indian film 'Fire in the Blood', directed by Dylan Mohan Gray is continuing for a third successful week at PVR Phoenix in Mumbai. Narrated by Oscar winner and four-time nominee William Hurt, 'Fire in the Blood' tells the story of how Western pharmaceutical companies and governments aggressively blocked access to low-cost AIDS drugs in the years after 1996, directly resulting in no less than 10 million avoidable deaths in Africa and various other parts of the global south. The movie portrays the monumental change brought about by the small, unlikely group of people who decided to fight back against this deeply unjust blockade.

Clinical Trials

Publication: The Indian Express
Editions: National
Date: 28.10.2013
Headline: Tried, tested and failed

Synopsis: Clinical trials would be more popular in India if they had safer, clearer protocols.

On October 21, after an undue delay of almost 10 months, the ministry of health, appearing before the Supreme Court, offered to get 157 concurrent global clinical trials of new chemical entities (NCEs) reviewed and approved by the technical and apex committees. These GCTs had been scrutinised only by the new drugs advisory committee (NDAC) and approved by the Central Drugs Standard Control Organisation (CDSCO) a few days before the Supreme Court order of January 3, 2013.

Publication: The Indian Express
Editions: National
Date: 28.10.2013
Headline: Drug trials: Lax regulations cost country dear

Synopsis: The demand for new drugs remains high, the cost and need to bring them to the market are also increasing. With an increasing life expectancy, the spotlight is now on how best to tackle hypertension, diabetes

and cancer and other non-communicable diseases. And it does hurt when patients in a global clinical trial getting high-end drugs to treat multiple myeloma — a cancer of the plasma cells — is suddenly withdrawn and sent to neighbouring Bangladesh!

Publication: Business Standard
Editions: National
Date: 27.10.2013
Headline: Clinical errors

Synopsis: The pharmaceutical sector has been hit by one crisis after another. The latest is the Supreme Court directive to the Union health ministry to review 157 clinical trials approved by the Central Drugs Standard Control Organisation. On January 3, after allegations of irregularity in the approval process came up, the Supreme Court had banned clinical trials for all new chemical entities unless they were personally vetted and cleared by the health secretary.

Publication: Business Standard
Editions: National
Date: 26.10.2013
Headline: Biocon criticises clinical trials' regulation

Synopsis: Biocon, the publicly-held biotechnology company, has criticised the regulatory framework guiding clinical trials in the country. Coming down heavily on the regulations on clinical research, Kiran Mazumdar-Shaw, CMD, Biocon Ltd, said it was adversely impacting clinical research in the country today.

FDA

Publication: The Economic Times
Editions: National
Date: 26.10.2013
Headline: FDA chief Margaret Hamburg's visit may soothe jittery nerves

Synopsis: At a time when leading Indian pharmaceutical companies have been cited for infringements by the US drug regulator, its chief Margaret Hamburg is planning her first visit to India, most likely later this year or early next year. Originally scheduled for October, the trip by the US Food and Drug Administration commissioner had to be postponed at the last moment because of the US "partial government shut down", a USFDA spokesperson confirmed to ET. n the last few months, there's been a spike in "violations" at Indian drug factories, according to data from FDA's Centre for Drug Evaluation and Research, the US drug safety office. The sites of drugmakers such as Ranbaxy Laboratories, Wockhardt and Strides Arcolab are on the list.

Publication: The Times of India
Editions: National
Date: 26.10.2013
Headline: FDA to check for illegal sale of abortion pills

Synopsis: The Kolhapur division of the Food and Drugs Administration (FDA) will initiate a drive to check the stock of abortion pills in chemist's shop across the district to prevent their misuse and illegal sales. The decision follows the Gandhinagar police arresting Shakuntala Ramrao Yadav, a homeopath, on Wednesday for her alleged involvement in carrying out illegal abortions. According to senior officials of the district health administration, Yadav was using these pills to abort foetuses. A stock of such pills was seized from her 'clinic'.

Publication: Business Standard
Editions: National
Date: 25.10.2013
Headline: Now, US FDA gets a call from Indian pharma companies

Synopsis: The Indian Pharmaceutical Alliance has approached regulator for a dialogue to understand the concern raised by it. The domestic pharmaceuticals 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 market accounts for highest revenue for the Indian drug industry. The Indian Pharmaceutical Alliance (IPA), which represents the domestic drug manufacturing industry, has approached the US FDA for a dialogue to understand the issues surrounding the industry, as well as the concern raised by the regulator. IPA has 19 members, including multinational companies such as Ranbaxy, Wockhardt, Sun Pharma and Lupin

Drug Regulatory

Publication: Mint
Editions: National
Date: 27.10.2013
Headline: India still to act on stationing drug quality inspection team in China

Synopsis: As foreign regulators strengthen surveillance of drug makers in India to make sure the medicines their countries import are safe, India is still to act on a proposal for stationing a drug quality inspection team in China, often suspected of dumping cheap and inferior quality pharmaceutical raw materials in India.
The proposal was supposed to be implemented by March this year, but as yet there is no clarity on when it will take off. The Indian drug industry imports almost 90% of its raw materials as well as medical devices from China, according to data from the industry and the Pharmaceuticals Export Promotion Council of India. The inputs sourced from unauthorized manufacturers in China have been cited among key quality concerns that foreign regulators, including the US Food and Drug Administration (FDA) and the UK's Medicines and Healthcare products Regulatory Agency (MHRA), raised about the Indian drug industry. Many of the inputs are sourced from unauthorized factories not approved by the Indian drug regulator, which means there is not much awareness of the quality standards they follow.

Publication: The Times of India
Editions: National
Date: 27.10.2013
Headline: DCGI to check on quality of India made medicines

Synopsis: At a time when the country is generating 26 billion US dollars from pharmaceutical industry alone, to keep a check on quality and enhance revenue, Drugs Controller General of India (DCGI) will be starting a worldwide check of Indian drugs, which are exported and produced for domestic consumption. Such a check/sampling is based on complaints from the west about spurious drugs made in India. On Friday, DCGI signed an MOU with IMTECH to provide standard and certified reference microbial cultures required for quality check of drugs in the industry.

Publication: The Hindu
Editions: National
Date: 27.10.2013
Headline: Clinical errors

Synopsis: There is always a scope to innovate, discover and improve the availability of medicines for various ailments. The global pharmaceutical industry is expected to grow at a 3 – 6 per cent compound annual growth rate (CAGR) over the next five years. The focus is on addressing unmet medical needs, making medicines more affordable and optimising manufacturing processes. The traditional understanding of quality as mere absence of defects has undergone a paradigm shift. Given that pharma products directly impact the human body, quality has much more significance here than in other industries. During the production process, the manufacturers strive to comply with global regulations and ensure safe and reliable drugs — all this while keeping the production costs at optimum levels. Pharma companies look at many sides to quality through many components including reviewing processes, regulatory requirements and good manufacturing practices. In order to tackle these challenges, quality is typically broken into several functions including quality assurance (QA), quality control (QC) and compliance.

Publication: Financial Chronicle
Editions: National
Date: 27.10.2013
Headline: UK regulatory curbs to cost Wockhardt £9 million in sales

Synopsis: Profit drops 69 per cent during July-September quarter. Mumbai-based pharma company Wockhardt, whose consolidated net profitdropped 69 per cent during the July-September quarter, would see an estimated impact of £9 million on revenues on an annualised basis, after the United Kingdom Medicines and Healthcare products Regulatory Authority (MHRA) has issued a restricted GMP certificate for the Chikalthana facility.

Publication: Pharmabiz
Editions: Online
Date: 28.10.2013
Headline: TN Pharmacy Council's ADR committee yet to start functioning even after 3 years

Synopsis: The adverse drug reaction committee (ADR Committee) constituted by the Tamil Nadu Pharmacy Council has not started functioning and no drug reaction report was made even after three years of formation. Deans of medical colleges, HoDs of departments of medicine, pharmacology, pharmaceutics, drugs control director and director of public health are other members of the Committee. The reports made by the committee have to be sent to the DCGI who will in turn collect information from the concerned manufacturing companies of the drugs reported and finally send to the testing lab of the All India Institute of Medical Sciences (AIIMS) for testing.

Publication: Pharmabiz
Editions: Online
Date: 28.10.2013
Headline: Health ministry finalises 'Biomedical Research Human Subjects Promotion and Regulation Bill'

Synopsis: After dilly-dallying on the subject for the last more than nine years, the union health ministry has finalised the 'Biomedical Research Human Subjects Promotion and Regulation Bill', which seeks to protect the human subjects used in any form of scientific research – behavioural or intrusive - done by an academic institution or pharmaceutical company. The bill seeks to protect these human subjects. At present, the research on human participants have been guided by the draft guidelines announced by the ICMR long back and the approvals given by the DCGI.

FDI

Publication: NDTV
Editions: Online
Date: 27.10.2013
Headline: FDI in August dips 38% to $1.4 billion, lowest in last 8 months

Synopsis: Foreign Direct Investment (FDI) into India declined to 8-month low of $1.4 billion in August, down 38 per cent year-on-year. The sectors that helped in registering the hike during the five months include services ($1.19 billion), pharma ($1.07 billion), automobile ($661 million) and construction ($592 million).

Publication: Financial Chronicle
Editions: National
Date: 26.10.2013
Headline: More than rate cut, we need higher savings

Synopsis: Nimesh Shah, MD and CEO, ICICI Prudential AMC, says while a select few stocks have seen huge FII interest and gone up substantially, the rest of the market remains largely under-bought and cheap in value terms. In an

interview with Bijoy Sankar Saikia, Shah also advises investors to look at companies that have the potential to raise capacity quickly without any increase in capex. An analysis of data for the last six years (October 2007-2013) indicated that while the broader market has gone up by a modest 2-3 per cent, indices that represent consumer durables, pharmaceutical and technology have gone up many fold. While fast moving consumer goods (FMCG), pharma and technology have done very well, rest of the sectors have underperformed.

Publication: The New Indian Express
Editions: National
Date: 27.10.2013
Headline: Expert slams FDI in healthcare

Synopsis: Increased foreign direct investment (FDI) in healthcare has led to a steep rise in downstream costs and is putting public health in jeopardy, particularly in developing countries, says David Sanders, an expert on public health. Sanders, emeritus professor, School of Public Health at the University of the Western Cape, South Africa, is also a member of the global steering council of the People's Health Movement. He was speaking at a conference on 'Global Health Crisis' in the city on Friday. The conference was organised by Jana Arogya Andolana Karnataka at the Indian Social Institute. Sanders suggested that governments need to take healthcare to lower levels of society by appointing and training grassroots level workers to handle health issues and administer drugs. Sanders pointed out India needed to boost spending on healthcare from the current level of 1.2 percent of GDP.

Patents / Compulsory Licensing / Intellectual Property Rights

Publication: FirstPost - World
Editions: Online
Date: 26.10.2013
Headline: Singh meets Putin: Full text of India-Russia annual summit joint statement

Synopsis: Prime Minister Manmohan Singh who is in Russia for the 14th India-Russia Annual Summit: Deepening the Strategic Partnership for Global Peace and Stability held talks with Russian President Vladimir Putin. The sides underlined the significant potential for cooperation in such sectors as oil and gas, pharmaceutical and medical industry. The sides welcomed the creation of new institutional mechanisms by the Ministry of Education and Science of the Russian Federation and the Ministry of Science and Technology of India. These mechanisms would support Indo-Russian R&D projects with potential for technology development and generation of new intellectual property. These projects would be in conformity with national priorities of both countries, as identified under 12th Five Year plan of India and the Federal Targeted Programme "Research and Development in Priority Fields of Science and Technology Complex of Russia in 2014-2020".

Publication: Daily News and Analysis
Editions: National
Date: 27.10.2013
Headline: India battling AIDS with no money, drugs

Synopsis: Shortage of anti-retroviral therapy drugs forces treatment centres to turn back patients. India's fight against AIDS looks like a hollow story. The country has nearly 2.5 million Persons Living with HIV/AIDS (PLHAs) and the total budget for providing them with the symptom-suppressing anti-retroviral therapy is Rs 4.5 lakh. And now, the nation is facing a shortage of this anti-retroviral therapy (ART) and patients are being sent back by treatment centres. Though the recently-released documentary Fire In The Blood which tells the story of Western pharma majors and governments blocking access (using patent laws to increase profits at the expense of peoples' lives) to low-cost AIDS drugs for the poor causing more than 10 million unnecessary deaths shows India in positive light for standing up to the hegemony of the pharma majors, the ground-situation is completely different.

Publication: Pharma News PR Wire
Editions: Online
Date: 26.10.2013
Headline: Pharma News Capsules Oct 2013

Synopsis: More than two-thirds of the pharmaceutical patents awarded by India in the last three years were granted to foreign drug makers such as Pfizer Inc., Novartis AG and F Hoffmann La Roche Ltd , which have been critical of India's intellectual property rights (IPR) regime. The country issued 1,001 drug patents between April 2010 and March 2013, of which 771 were given to foreign drug makers, mainly from the US and Europe, according to data released last week by the Indian Patent Office (IPO).

Drug Pricing

Publication: The Times of India
Editions: National
Date: 28.10.2013
Headline: Tropical Botanical Garden Research Institute to rope in tribals for drug production

Synopsis: Though the first ever benefit-sharing project to develop a health drug with the help of tribals was shelved in 2008, discussions to revive the project are currently underway. In the first phase of the project, the herbs will be collected and cultivated by tribals in their respective areas. The produce will then be purchased by the government or a designated agency to ensure fair pricing and a means to support their livelihood, she said. The herbs will then be used to develop drugs or health tonics, she said.

Publication: The Telegraph
Editions: National
Date: 26.10.2013
Headline: Tablets And Table Fans

Synopsis: Drug regulation has also been ineffective; witness the massive fines levied on blue chip Indian pharmaceutical companies (like Ranbaxy) by the Food and Drug Administration of the United States of America for false test claims, poor hygiene and so on. This hurts the perception of all Indian pharmaceutical manufacturers. Easy availability of dangerous drugs to anybody is another example. The poor availability of electricity in India deters fresh investments. Use of technology is haphazard, except in some states like Gujarat. An 'independent' regulator, the National Pharmaceutical Pricing Authority, determines prices of drugs, again in a non-transparent way.

Publication: The Hindu
Editions: National
Date: 26.10.2013
Headline: Fading judicial independence

Synopsis: The 120th Amendment Bill 2013 deviates from its U.K. model in the essential requirement of freeing judicial appointments from the executive. On October 6, 1993, the Supreme Court of India, in one stroke, became the most powerful Supreme Court in the world. The following two decades saw the court exercising its powers with complete confidence in its independence. It has read benevolent drug pricing into the patents regime.

Publication: Pharmabiz
Editions: Online
Date: 28.10.2013
Headline: Health Ministry planning to revise National List of Essential Medicines, 2011

Synopsis: Under pressure from different quarters including the Supreme Court over the impact of the new pharmaceutical pricing policy, the Union health ministry is planning to revise the National List of Essential Medicines

(NLEM-2011) which forms the basis of price control regime. The Health Ministry is learnt to have initiated steps to revise the list in accordance with the existing market conditions and usage of drugs by the patients. The Ministry may soon set up an expert group to suggest appropriate changes in the list of drugs so that the impact of the pricing policy could be reflected more effectively. Though the government had implemented the National Pharmaceutical Pricing Policy (NPPP) and issued the Drugs Price Control Order (DPCO) 2013 outlining the mechanism for price fixing, the issue is still under the scrutiny of the Supreme Court.