News Updates: November 23-25, 2013

Fire In The Blood

Publication: The Times of India
Edition: Ahmedabad, Online
Date: November 24, 2013
Headline: 'Lives more valuable than profits from drugs'

Synopsis: From psychological counselling in Kashmir to free healthcare in Somali conflict zones, Dr Unni Karunakara has endeavored to provide the best possible treatments in over 70 countries. Dr Unni Karunakara is the outgoing international president of Nobel peace prize-winning NGO, Medecins Sans Frontieres (MSF) or Doctors without Borders and has been working in international health for 18 years. Karunakara is on a 5,000-km bicycle tour of India. He stopped in Ahmedabad for the screening of a film, 'Fire in the Blood' - an account of medicine and monopoly, featuring MSF activists. On healthcare commercialization, he said: "It's disheartening that one section of society can afford and have access to healthcare while others have no access at all. Whenever lives and profits must be balanced, lives must be above profit. People in the US still cross borders to buy drugs. There is no research on paediatric HIV because incidence is low in the West, but it is a big problem."

Publication: IBNLive
Edition: Online
Date: November 23, 2013
Headline: 5 off-beat films everyone's talking about

Synopsis: Fire in the Blood: Dylan Mohan Gray's film has an India connection, which is not only relevant but also has a very important placement in our lives. This hard hitting documentary is about the monopoly of pharmaceutical companies on life saving drugs, and how these companies lobby to bend the rules to seek benefits.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Hindu Business Line
Edition: National
Date: November 23, 2013
Headline: Hepatitis C drug: US group opposes Gilead's patent request in India

Synopsis: US drug-maker Gilead Sciences' patent application on hepatitis C drug sofosbuvir has been opposed at the Indian Patent Office by legal group I-MAK — Initiative for Medicines, Access & Knowledge. The pre-grant opposition, where a patent application is opposed before a decision is taken, was filed at the Kolkata patent office. Gilead's patent application has been opposed on the grounds that it is an "old science, known compound," said Tahir Amin, lawyer and director of US-based I-MAK.org.

Publication: Financial Times
Edition: Online
Date: November 24, 2013
Headline: Indian health activists move to prevent Gilead's drug patent

Synopsis: Indian health activists are seeking to prevent Gilead from patenting its new treatment for Hepatitis C in the country in a fresh battle over affordable access to medicine. The Initiative for Medicines, Access & Knowledge in India said it had filed a "pre-grant" application in Calcutta to block a patent application on the drug sofosbuvir, just as Gilead, the US pharmaceutical group that developed the medicine, won European regulatory authorisation for its

use.The legal action, which follows previous spats in India over intellectual property on medicines including those for HIV and cancer, could open the way for local generic drug manufacturers to sell low-cost versions of the product domestically and export it to other low-income countries without strong patent protection laws. The move would be a blow to Gilead, which is spearheading a race for new, more effective oral treatments for Hepatitis C with fewer side-effects, widely viewed as having the potential to cure Hepatitis C, a condition that affects nearly 200m people around the world and causes damage to the liver and sometimes cancer. Following its European approval for drug, branded as Sovaldi, Gilead is braced for regulatory authorisation in the US next month. Other drug companies including AbbVie, Johnson & Johnson and Bristol-Myers Squibb are competing with experimental products for the condition in a market that analysts forecast could generate billions of dollars in annual sales. “Old science, known compound,” said Tahir Amin, lawyer and director at the I-MAK, the group that filed the opposition. “India’s patent law doesn’t give monopolies for old science or for compounds that are already in the public domain. We believe this patent on sofosbuvir does not deserve to be granted in India.”The legal action could stall for several years the granting of patents in India, which one generic drug manufacturer said could permit the production of low-cost equivalents over several years. Médecins Sans Frontières, the humanitarian organisation, said it welcomed the legal challenge, expressing concern that even at a significant discount to the estimated $80,000 US price for the drug treatment, it would be inaccessible to the vast majority of Hepatitis C patients who live in low and middle income countries. Dr Simon Janes, medical co-ordinator with MSF in India, said: “We know from our experience providing HIV treatment over more than a decade in dozens of developing countries that treatment needs to be simple and affordable – preferably less than $500 to start with. An unaffordable price for this drug will have a chilling effect on funders and governments who need to start financing and providing treatment.” Gilead has in the past sought to develop an access programme for patients in low-income countries by licensing its HIV drugs to generic manufacturers while controlling for quality. “As Gilead [Hepatitis C] medicines advance through the research and development pipeline, we will evaluate opportunities to incorporate them into our access programmes,” the company said on its website.

FDI

Publication: The Economic Times *(Reproduced from PTI)*
Edition: National
Date: November 24, 2013
Headline: **Cabinet may decide on FDI in pharma, housing tomorrow**

Synopsis: The Cabinet is expected to take a decision tomorrow on relaxing FDI norms for the housing sector and reducing foreign direct investment cap to 49 per cent in critical areas of the pharma segment. Several departments including the DIPP have raised serious concerns over continuous acquisitions of Indian drug makers by global multinational firms. "The Cabinet will review the FDI policy in pharmaceutical and housing tomorrow," an official said. The Department of Industrial Policy and Promotion (DIPP) has proposed to reduce FDI cap from 100 per cent to 49 per cent in the "rare or critical pharma verticals". There is thinking in the government that with MNCs taking control of Indian firms, there could be reduction in supply of vaccines, injectables, particularly for cancer and active pharmaceutical ingredients. Currently, India permits 100 per cent FDI in the pharma sector through automatic approval route in the new projects, but the foreign investment in existing pharma companies are allowed only through FIPB's approval.

Publication: The Financial Express
Edition: National
Date: November 24, 2013
Headline: **Monaco invites Indian firms to invest in IT, pharma sectors**

Synopsis: Monaco government today invited Indian companies to invest in various sectors, including information and technology, pharmaceuticals and real estate. "We are interested in participation of Indian companies in Monaco and there is a good atmosphere for their participation in all aspects of economic cooperation like information and technology, pharmaceuticals and real estate and tourism," Monaco Ambassador to India Patrick Medecin told reporters here. Over the years, Monaco has attracted FDI investment from Europe and America. The country is looking at talent from India for developing its R&D in pharmaceutical and IT sectors, Medecin said, adding that Monaco has people from around 120 nationalities working in various sectors and they enjoy no taxation benefits.

Publication: Daily News and Analysis
Edition: New Delhi, National
Date: November 23, 2013
Headline: Govt plans to tighten pharma sector M&As

Synopsis: The government would review its foreign direct investment (FDI) policy in pharma and realty sectors as it seeks to improve and allay fears over investment environment in the country. The Cabinet Committee on Economic Affairs, set to meet on November 25, will consider the contentious issue of FDI in the pharma sector, which has seen three ministries war over allowing the entry of foreign players in the country. While the health and commerce ministries want more restrictions over takeovers of existing companies by foreign players, the finance ministry is for giving free hand to foreign players to improve the investment environment of the country. The Parliamentary Committee on Commerce on FDI in the pharmaceutical sector had asked for imposing a blanket ban on foreign investment in brownfield pharma projects. At present, 100% FDI is allowed in new projects through the automatic route in the pharmaceuticals sector, while 100% is also allowed in existing facilities, subject to government's permission, said the Committee.

FDA / Drug Regulatory / DCGI / Drug Policy

Publication: The Times of India
Edition: Hyderabad, National
Date: November 23, 2013
Headline: Sanofi Aventis arm drags DRL to court

Synopsis: Drug major Sanofi-Aventis's arm Genzyme Corporation along with the Southern Research Institute (SRI) has sued pharma giant Dr Reddy's Laboratories for infringing upon the patent of its cancer drug, Clolar. DRL and its US subsidiary DRL Inc have been sued by Genzyme and SRI in the US District Court for the District of New Jersey after they filed an abbreviated new drug application (ANDA) with the United States Food and Drug Administration (USFDA) seeking approval to market Clofarabine in the injectable form, which is a generic version of the drug, before the expiration of its patent on January 14, 2018. According to Genzyme, the patent (number 5,661,136) belongs to Southern Research and it (Genzyme) holds exclusive rights to market Clolar and the two companies would be "substantially and irreparably" harmed if DRL is not restrained from launching the copycat version of their patented drug in the US market.

Publication: The Times of India
Edition: National
Date: November 23, 2013
Headline: 'Ask your doctor about a drug's side-effects'

Synopsis: Dinesh Thakur, who blew the whistle on the wrong-doings in India's largest drug company Ranbaxy, is now using his domain knowledge to help the pharma industry to mitigate risk in the global supply chain, and comply with the complexities of US law. Post the Ranbaxy expose, he is now focused on creating a second US-based startup which will aid pharma companies in their sourcing from low-cost locations like India, China and Latin America. In an interview to TOI, he feels that to counter the "trust-deficit" in the industry, and specifically on life-saving medicines, there is a need for the drug regulatory framework in India to be harmonized with internationally-accepted standards, and for the patient to be more informed. "Our assessment framework enables pharma companies to assess sources of risk within their supply chain and proactively manage those risks, rather than waiting for a regulator to identify them, and penalize the manufacturer. It is a whole lot more expensive to react to a warning letter than to proactively fix whatever issues you have," he adds.

Publication: The Financial Express
Edition: National
Date: November 25, 2013
Headline: Obamacare, buyouts boost India's tally of ANDAs

Synopsis: A fiscally stressed Washington's policy support to low-priced alternatives to innovator drugs and a flurry

of recent acquisitions have helped Indian drug companies outdo their American counterparts in the latter's home turf in securing approvals for generic medicines. According to the US Food and Drug Administration (FDA) data reviewed by FE, one in four abbreviated new drug applications (ANDAs) approved by the regulator in 2012 belonged to an Indian company, a shade better than the performance by the US generic drug companies led by Mylan and Watson Labs. Available data for this year (till October-end) have only cemented India's lead.

Publication: Business Standard
Edition: National
Date: November 25, 2013
Headline: Ranbaxy may sell off Biovel, exit vaccine business

Synopsis: Drug maker Ranbaxy Laboratories is likely to sell off Biovel, a Bangalore-based vaccine manufacturing company which it had acquired in 2010, sources said. Although Ranbaxy made the acquisition to foray into the vaccine business, it failed to roll out any product in the segment for the past two years. The company recently booked impairment losses on account of Biovel. Following the US Food and Drug Administration (US FDA) enforcement on various Indian factories of Ranbaxy, there is a financial pressure on the company's accounts. The company's business has suffered because of regulatory issues through past years. Besides, it also had to incur additional costs to settle those issues.

Publication: NDTV
Edition: Electronic, Online
Date: November 25, 2013
Headline: The NDTV Dialogues: Why is India's healthcare in critical condition?

Synopsis: India's health parameters are amongst the worst in the world right now and a child born in India today has less chances of survival than in Nepal or Bangladesh. Essential drugs are something, which all we've been talking about, that is being setup very effectively in certain aspects. And one of the important things in healthcare is not just something that happens through a union policy, it is to be delivered at the state level, so states also get involved in health delivery.

Publication: The Hindu Business Line
Edition: National
Date: November 22, 2013
Headline: We are open to building our competencies inorganically: Wipro

Synopsis: The pharma industry is faced with increasing spend on compliance ($110 billion estimated), owing to increasing FDA screenings and regulatory laws. This implies that pharma companies need to put in place business compliance solutions to provide data, transparency and access to meet various regulatory laws like sunshine, e-pedigree and safety reporting. Wipro is enabling pharma companies in reducing the cost of compliance through process automation and standardisation. The traditional focus- on-pill sales and marketing model is under increased pressure, owing to the 'Patent cliff' – resulting in a significant loss of revenues, and increased focus on total health outcomes for determining formulatory status. As a result, pharma companies are being driven to offer patient-centric services that help with specialised areas like self-monitoring tools, disease awareness programmes, drug authentication tools, overall disease care and management and access to expert community, thus offering a way to impact the health outcome and also provide an additional revenue source in view of patent expiry.

Publication: The New Indian Express
Edition: National
Date: November 24, 2013
Headline: Drugs illegally made, sold in Puducherry

Synopsis: Over 500 combination drugs, which have not been permitted by the Drug Controller General of India (DCGI), are being produced by drug manufacturing firms and sold in the market in Puducherry. After it was

ascertained that these drugs are not tested for safety and efficacy and could be potentially dangerous, the Health Department has issued showcause notices to 20 units for manufacturing such illegal combination drugs, G Ragesh Chandra, Secretary Health also functioning as Drug Controller of Puducherry, told Express.

Publication: Pharmabiz
Edition: Online
Date: November 23, 2013
Headline: Need for a change in mindset to meet regulatory challenges in India: Experts

Synopsis: In order to meet the challenges faced by Indian companies on account of non-compliance in terms of CGMP norms, experts deliberated that Indian pharma companies need to adopt a policy of self control and as far as possible get the required expertise to resolve regulatory challenges. Potential solutions to challenges faced by exporters to regulated markets; stumbling blocks faced while making abbreviated new drug applications and how to overcome them; quality standards and certification available to grade pharmaceutical excipients in the current regulatory scenario were some of the major topics discussed on the occasion of the second edition of EMPROVE Seminar Series held in Mumbai on November 21, 2013 organised by Merck Millipore, the Life Science division of Merck, under the theme 'Stability in Turbulent Times'. Said Pharma Industry Analyst Tapan Ray on the sidelines of the seminar, "The country has witnessed an increasing trend of import bans and people have started generalising India with violations of CGMP norms and falsification of data."

Drug Pricing

Publication: The Hindu Business Line
Edition: National
Date: November 24, 2013
Headline: There's no thought of going public: Cadila Pharma

Synopsis: Indian pharmaceutical companies are often criticised for not focusing enough on new drug development. Rajiv Modi, Chairman, Cadila Pharmaceuticals, begs to differ — he hopes that in his lifetime the company will put at least 10 new drugs in the market. "We have made huge investments in the US because we are geared up to package our products to make sure our launch happens smoothly." Rajiv Modi, Chairman, Cadila Pharma. The Government has taken a very strategic step and increased the number of products under price control significantly.We, as a company, never sold products at the highest price. So, in a way, Cadila is affected only partly for some drugs. On the rumour about an MNC picking up a stake in Cadila, it's a big No. It is because they (market) are seeing a lot of visibility in the house. Our growth story comes after so many failures. There is no thinking about a stake sale, as we believe our philosophy and fundamental will be destroyed. If you become public then other external pressures come in.

Publication: Business Standard
Edition: National
Date: November 23, 2013
Headline: More essential drugs get duty exemption

Synopsis: The government has extended a 30-day excise duty exemption for re-packaging of essential medicines to the batches whose prices were revised in July, August and September. In July, the finance ministry had exempted excise duty only on the first batches of scheduled drugs whose prices were fixed in May and June after the National Pharmaceutical Pricing Authority (NPPA) implemented the new Drugs Price Control Order (DPCO). According to this, prices are capped at the average price of all medicines in a particular segment with a market share of at least one per cent.

Publication: Financial Chronicle
Edition: National
Date: November 25, 2013
Headline: Pfizer-Wyeth merged entity to be among top 10 players

Synopsis: As the Indian operations of Pfizer Inc and Wyeth finally merge, nearly five years after Pfizer Inc acquired Wyeth globally in one of the mega acquisitions in the pharma history for a mammoth $68 billion, the new combined entity -- a single brand under Pfizer, will de-risk business profile in the country and have increased share in therapeutic areas. Going by the current new drug pricing policy and foreign exchange volatility, Wyeth had a bigger impact compared to Pfizer, though both had been impacted by the trade-margins related issues in the market place, Aijaz Tobaccowala, MD, Pfizer said.

Publication: Pharmabiz
Edition: Online
Date: November 25, 2013
Headline: Supreme Court to resume hearing case against market-based drug pricing on Nov 25

Synopsis: The much delayed hearing on market-based drug pricing v/s cost-based drug pricing case between the central government and a host of public interest groups will be resumed in Supreme Court on November 25. The hearing in the case is at a crucial stage as the Supreme Court bench headed by Justice G S Singhvi has agreed to evaluate the new National Pharmaceutical Pricing Policy and the new Drug Price Control Order (DPCO) 2013. The court, during the last hearing, had directed the public interest groups, who are fighting for a feasible drug price mechanism, to submit a detailed affidavit to prove how the new pricing policy has adversely affected the drug prices.

Publication: Pharmabiz
Edition: Online
Date: November 25, 2013
Headline: Govt considering to have separate pricing policy for biosimilars soon

Synopsis: The Government is planning sector-based pricing mechanism for different streams of drugs like biosimilars which are getting popular in the country but not governed by the pricing norms that are applicable to the chemical-based drugs. The Government is also planning to set up a mechanism involving the stakeholders to streamline the issues in the biosimilar sector. The joint body between the government and the industry will meet every quarter to address the emerging issues. While addressing an industry meet here recently, Joint Secretary in the Health Ministry Arun Kumar Panda gave the indication of introducing a separate price regime for the biosimilars. He also called for fast tracking the biological as done for the generic drugs in the past so that drugs and vaccines could be made affordable. National Pharmaceutical Pricing Authority (NPPA) chairman C P Singh also backed the idea of separate pricing systems. The drugs pricing formula in India is too general under the current regime and needs to be sector-based, especially for fixing prices of biopharmaceuticals, he noted.

Publication: Pharmabiz
Edition: Online
Date: November 25, 2013
Headline: NRHM pushing generic drugs through different flagship programmes, says Mission Director

Synopsis: An amount of Rs.5000 crore is being spent this year for the universal health coverage with a push to the generic drugs, through the National Rural Health Mission, flagship programmes and otherwise, according to additional secretary and NRHM mission director Anuradha Gupta. “It is not correct that we are not pushing the generic drugs. We have allocated Rs.3500 crore under the universal health coverage and taken all efforts to promote generic drugs. We have directed all the States in this regard,” Gupta told Pharmabiz on the general complaint that NRHM was not giving adequate spur to generic drugs. Out of the total sanctioned amount of Rs.3500 crore so far, Rs.2000 crore was allotted only for drug purchase and the Government had asked the States give priority to generic drugs. Most of the States have implemented the projects in this line, she added. According to the estimates by the Planning Commission, a total of Rs.30,000 crore was required for the programme during the current 12th Five Year Plan period. The government had finally approved Rs.16,000 crore for buying the generic drugs under different central and state health programmes for the period.

General Industry

Publication: Business Standard
Edition: Online
Date: November 21, 2013
Headline: Inorganic investments likely in pharma R&D: ICRA

Synopsis: In particular, fast-growing branded generics markets in South-East Asia, Latin America and even some of the markets in East Europe will be of interest to Indian companies. In the backdrop of increased investment on research and development (R&D) by Indian pharmaceutical companies, market research firms like ICRA expect in-organic investments to gain momentum in the medium term.In a recent report, ICRA highlights that as Indian pharma companies have developed capabilities to target complex segments like injectables, inhalers, opthalmics and even biosimilars, they have been investing a higher proportion (around 6.5 to 8 per cent) of their sales in R&D activities over the past few years. In particular, fast-growing branded generics markets in South-East Asia, Latin America and even some of the markets in East Europe will be of interest to Indian companies. "Besides, market-entry driven acquisitions, we also expect investments to add technical capabilies in selected therapy areas or delivery systems to also continue going forward in view of increasing focus on complex generics," ICRA said.

Clinical Research / Trials

Publication: The Hindu Business Line
Edition: National
Date: November 23, 2013
Headline: Videorecording of consent for clinical trials mandatory

Synopsis: The Union Health Ministry has made audio-visual recording of the informed consent of each subject mandatory in a clinical trial. This is in addition to obtaining his/her written consent. This decision comes in the wake of the Supreme Court pulling up the Ministry for lack of transparency in clinical trials. In its October 21, 2013, order on a writ petition filed by an NGO, the Swasthya Adhikar Manch, Indore, the court said with respect to five global clinical trials, which was approved by the Drugs Controller-General of India (DCGI) office from January 1, 2013, to August 31, 2013, an appropriate provision should be made or administrative direction issued, ensuring that audio-visual recording of the informed consent process was done and the documentation preserved, adhering to confidentiality principles.