News Updates: December 13, 2013

Drug Pricing

Publication: The Economic Times
Edition: Mumbai
Date: December 13, 2013
Journalist: Soma Das
Headline: Retailers, Pharma companies fail to agree over margins of price-controlled medicines

Synopsis: Pharmaceutical companies have failed to arrive at an agreement with drug distributors and retailers on the margins of price-controlled medicines, potentially jeopardising the smooth roll-out of the new pricing policy across the country. Domestic drug makers have alleged that distributors and retailers are planning to boycott three leading companies Sun Pharma, Cadila Healthcare and Abbott from Sunday. All India Organisation of Chemists and Druggists (AIOCD) has threatened to boycott products of Sun Pharma, Cadila Healthcare and Abbott, starting 15th of this month, said DG Shah, secretary general of Indian Pharma Alliance, a grouping of leading local drugmakers. These three companies collectively command 17% market share in the highly fragmented.72,000 crore domestic drug market.

Publication: The Economic Times
Edition: Print, Online *(Report shared yesterday. Appeared in Mumbai and Kolkata print edition today as well)*
Date: December 13, 2013
Headline: Supreme Court ruling on GSK sends drug sector into huddle

Synopsis: Pharmaceutical companies, already hurting from a slowdown in the Rs 72,000 crore domestic drug market, face the prospect of penalties running into hundreds of crores of rupees if deemed to have overcharged for pricecontrolled drugs for well over a decade. This concern has emerged in the wake of the Supreme Court ruling on Monday that unsold medicine stocks from previous batches cannot be sold at higher unrevised prices after the cut-off date fixed by the drug price regulator. The National Pharma Pricing Authority (NPPA) is studying the judgement and will begin the exercise of calculating the amount overcharged by drug companies soon.

Publication: Business Standard
Edition: National
Journalist: Ujjval Jauhari & Ram Prasad Sahu
Date: December 13, 2013
Headline: Pharma MNCs: Pricing, regulatory clarity a boost

Synopsis: Higher volumes could see these companies reverse their underperformance cycle vis-à-vis the industry. While multinational pharmaceutical companies have been laggards on the returns charts through the past few years vis-à-vis their large-cap Indian peers, it is expected they will bridge the gap due to regulatory clarity and operational gains. The interest in pharma MNCs has increased through the last few months, considering the government has retained the 100 per cent foreign direct investment (in completely new projects, as well as in those already in progress) clause and there is clarity on pricing. These factors have started reflecting on their stocks, which have, through the last one-three months, risen six-21 per cent.

FDI / Foreign Investment in Pharma / M&As in Pharma

Publication: The Hindu Business Line
Edition: Online
Journalist: Amiti Sen
Date: December 13, 2013
Headline: 2 FDI proposals worth Rs 98 cr approved

Synopsis: The Government has approved two Foreign Direct Investment (FDI) proposals — one each in the pharmaceutical and civil aviation sectors — worth Rs 97.85 crore. Acebright Pharma, a foreign-owned Indian pharmaceutical company, received approval for additional investment by way of fresh issue and transfer worth Rs 95 crore.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Times of India
Edition: Mumbai
Date: December 13, 2013
Headline: State braces for 3-day chemists' strike from Monday

Synopsis: Chemists on Thursday stayed away from a meeting with Food and Drug Administration (FDA) officials who were hopeful of a last-ditch attempt to stop them from going on a three-day strike. Around 55,000 chemists across the state have threatened to keep their shops shut from December 16 to 18. The business community has been protesting against FDA's crackdown on unlawful practices and non-adherence to rules. "There is no question of backing off from the protest. The draconian interpretation of Drug and Cosmetics Act has made it difficult for chemists to operate," said Damji Palan, president, Retail & Dispensing Chemists Association. The association members have suggested that people should stock up on their routine medication to avoid health issues.

Publication: The Times of India
Edition: Online
Date: December 13, 2013
Headline: Pharmacist-owned shops not to join drugstores strike

Synopsis: For the first time, there is a clear split between pharmacist-owned drugstores and others over the proposed state-wide strike of medicine shops from December 16 to 18. While the Food and Drugs Administration (FDA) is asking associations of both not to go on strike, the associations are busy making allegations against each other. Maharashtra Chemists and Druggists Association (MSCDA) has called for the strike to protest 'undue harassment' by FDA in the name of implementing the Drugs and Cosmetics Act 1940 and wrong cancellation and suspension of licences in the past two years. The association secretary Anil Navander told TOI that his association was not against mandatory presence of a pharmacist at every shop but were only opposed to FDA's unrealistic and impractical approach in implementing the Act.

Publication: Daily News and Analysis
Edition: Online
Date: December 13, 2013
Headline: Association forcing us to go on 3-day strike, 20,000 chemists write to Prithviraj Chavan

Synopsis: While miscreant chemists are threatening to hold the state to ransom for three days come December 16, their honest counterparts have appealed to the state government to take the strictest action against those who shut shop in a bid to deprive patients of medicines. Of the 55,000 chemist shops in Maharashtra, around 20,000 chemists will defy the call for a strike and keep their shops open. On December 7, some chemists wrote to the chief minister Prithviraj Chavan stating that they were being coerced by the Maharashtra State Chemists and Druggists Association (MSCDA) to forcefully shut shop despite their unwillingness to participate in the pan-state strike. Up to four associations are opposing the strike in Maharashtra, including Akhil Bhartiya Pharmacists Welfare Association, Pharmaceutical Teachers Association, Hospital Pharmacists Association and Union of Registered Pharmacists (URP).

Publication: The Financial Express
Edition: National
Date: December 13, 2013
Headline: USFDA approves generic version of anti-depressant

Synopsis: The U.S. Food and Drug Administration today approved the first generic versions of Cymbalta (duloxetine delayed-release capsules), a prescription medicine used to treat depression and other conditions. Aurobindo Pharma Ltd., Dr. Reddy's Laboratories Ltd., Lupin Ltd., Sun Pharma Global FZE, Teva Pharmaceuticals USA, and Torrent Pharmaceuticals Ltd. have received FDA approval to market duloxetine in various strengths. "Health care professionals and consumers can be assured that these FDA-approved generic drugs have met our rigorous standards," said Kathleen Uhl, M.D., acting director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. "Generic drugs offer greater access to health care for many people."

Similar reports have appeared in the following:

- **Business Standard-** Nod for anti-depressant cheers Indian pharma
- **The Hindu -** FDA clearance for generic versions of anti-depressant drug Cymbalta
- **Financial Chronicle –** 5 Indian Companies get FDA nod for anti-depressant drug
- **The Indian Express -** Several Indian Cos Get FDA Nod for Anti-depressant Drug

Publication: The Hindu Business Line *(Editorial)*
Edition: National
Date: December 13, 2013
Headline: A prescription for equality

Synopsis: As India aligns itself with global best practices and offers greater market access and stronger intellectual property protection as investment-luring carrots to multinationals, it also needs to also crack the whip on getting companies to do the right thing for the Indian consumer. This requires amending the Drugs and Cosmetics Act. Regulatory provisions governing product or drug recall, as well as guidelines for compensation, need to be re-aligned with the rest of the developed world. The need for strong regulatory supervision is especially pressing, since most patients lack the resources to pursue cases in courts. If multinational companies are to be given a level playing field for doing business in India, then regulators must ensure that patients also get equal treatment in terms of protection of their rights.

Publication: The Free Press Journal
Edition: Hyderabad
Date: December 13, 2013
Headline: Pharma cos get FDA nod for drug

Synopsis: The US Food and Drug Administration has approved the first generic versions of Cymbalta (duloxetine delayed-release capsules), a prescription medicine used in treatment of depression and other conditions. Aurobindo Pharma, Dr Reddy's Laboratories, Lupin, Sun Pharma Global FZE, and Torrent Pharmaceuticals have received the regulatory nod to market duloxetine in various strengths, besides Teva Pharmaceuticals

Publication: Pharmabiz
Edition: Online
Date: December 13, 2013
Headline: DCGI ask drug cos to provide details about import alert or restrictions on their products by authorities abroad

Synopsis: The drugs controller general of India (DCGI) has asked the pharmaceutical companies in the country to bring details about drug import alert or restrictions imposed by regulatory authorities abroad against them to the immediate notice of DCGI office as well as the state drug control authorities. The DCGI's action in this regard is aimed to ensure quality, safety and efficacy of the drugs marketed in the country.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: Mint *(Reproduced from Bloomberg)*
Edition: National
Date: December 13, 2013
Headline: Dr. Reddy's Targets Roche's Rituxan in Europe

Synopsis: Dr. Reddy's Laboratories Ltd. (DRRD), India's second-largest drugmaker, aims to be among the first three to four companies offering copies of biotechnology drugs, including a version of Roche Holding AG (ROG)'s Rituxan, in Europe. A partnership the Hyderabad-based company struck with Merck KGaA (MRK)'s Merck Serono unit last year to develop cheaper copies of biologic cancer drugs could yield products in Europe in four years, Dr. Reddy's Managing Director Satish Reddy said in an interview in Mumbai.

Publication: The Hindu Business Line
Edition: National
Date: December 13, 2013
Headline: Cadila in pact with Warner Chilcott to settle US patent issue

Synopsis: Cadila Healthcare Ltd and Zydus Pharmaceuticals (USA) Inc. have entered into an in-principle agreement with Warner Chilcott to settle all outstanding patent litigation related to bowel disorder drug Asacol. Warner Chilcott had lodged a suit in the Delaware federal court, US, in 2011, seeking to stop Cadila and its US unit from launching a generic version of the drug. Warner Chilcott is a Puerto Rico-based pharmaceutical company. It had filed the suit in response to the filing of an abbreviated new drug application (ANDA) by Cadila and Zydus that sought to market a generic version of the drug before the expiration of Warner's patent.

Publication: The Hindu Business Line
Edition: National
Date: December 13, 2013
Journalist: P T Jyothi Datta
Headline: BMS-Medicines Patent Pool pact opens up manufacture of generic versions of AIDS drug

Synopsis: Indian drug makers wanting to make AIDS drug atazanavir, will now be able to do so, following a licensing agreement signed by multinational drug-major Bristol-Myers Squibb and the United Nations-backed Medicines Patent Pool. BMS' drug atazanavir is used in the second-line treatment of HIV/AIDS. And the agreement, announced on Thursday, will allow manufacturers world-wide to produce more affordable versions of atazanavir, and to combine atazanavir with other medicines to make treatment easier and more accessible in developing countries, said Greg Perry, Executive Director of the Medicines Patent Pool (MPP).

Similar reports have appeared in the following:
- **The Times of India – Medicines Patent Pool, BMS sign agreement to increase access to key HIV medicine**
- **Reuters India - Bristol adds medicine to patent pool for AIDS drugs**

Publication: Financial Chronicle
Edition: National
Journalist: Trushna Udgirkar
Date: December 13, 2013
Headline: Astrazeneca sues Aurobindo over infringement of patent

Synopsis: Biopharmaceutical company Astrazeneca has sued Indian drug maker Aurobindo Pharma over a possible patent infringement of their product –Nexium. The drug is used for treatment of gastroesophageal reflux disease. Aurobindo had filed for an ANDA (Abbreviated New Drug Application) with the USFDA to seek an approval to manufacture the copy cat version of drug and market it in the US, this October. The complaint is filed in the US District Court for the district of New Jersey, earlier this month. To market and sell this drug in the US, Astrazeneca has tied up with Delaware based KBI – E Inc.Astrazeneca LP holds the New Drug Application No. 21153 for NEXIUM which is are Esomeprazole Magnesium delayed-release tablets.

Publication: MoneyControl
Edition: Online
Date: December 12, 2013
Headline: Another big patent expiry, limited gains for generics

Synopsis: Latest patent expiration of Eli Lily's anti-depressant drug Cymbalta, which had annual US sales of USD 5.5 billion, has not materialised as anticipated by the Indian generic drug makers, reports CNBC TV18's Archana Shukla. While Indian generic majors Sun Pharma , Dr Reddy's Lab , Aurobindo Pharma , Lupin and Torrent have all secured US FDA approval, along with Israeli firm Teva Pharma to market generic versions of Cymbalta, it is now anticipated to be a tough competition. According to the US FDA website, another four generic filers are awaiting approvals from the US FDA for this drug which treats depression and anxiety disorders.

Publication: IANS
Edition: Online
Date: December 12, 2013
Headline: US-India ties to keep growing despite elections

Synopsis: The India-US partnership would continue to grow in its intensity regardless of the upcoming parliamentary elections in India next year or the losses suffered by Congress-led ruling coalition in the recent assembly elections. This appeared to be the key outcome of Foreign Secretary Sujatha Singh's just concluded four day visit during which she held "exceedingly useful and very productive" discussions with top Obama administration officials and lawmakers from both Democratic and Republican parties. Singh also told officials what New Delhi was doing to address US business concerns mainly relating to Intellectual Property Rights (IPR), compulsory licensing in pharmaceuticals and FDI.

Clinical Trials

Publication: The Hindu
Edition: National
Date: December 13, 2013
Headline: Chennai hospital gets approval for clinical trials

Synopsis: The drug controller general of India has granted approval to Dr. K.M. Cherian's Heart Foundation and Frontier Lifeline Hospital to conduct clinical trials of their tissue-engineered porcine pulmonary artery, tissue-engineered bovine jugular vein and tissue-engineered bovine pericardium. Heart Foundation has been given permission to carry out clinical trials on human beings.

Publication: Deccan Chronicle
Edition: Online
Date: December 13, 2013
Headline: Clinical trials to be on-camera

Synopsis: Patients opting for clinical trials must give their consent to undergo the trials before an audio-visual camera, which will ensure that all the questions from the consent form are read out and understood. As the consent form runs into four pages, the boxes are currently checked and evaluation is done by para-medical staff or junior doctors. However, in case of camera recordings, all the questions have to be understood and accepted. In case of a dispute, the reasons need to be specific and patients must be allowed to voice their concern.

General Industry

Publication: Hanosphere.org
Edition: Online
Date: December 13, 2013
Headline: Science, vaccines and women's health suffer deadly setbacks in India

Synopsis: Seattle-based PATH, which in 2009 attempted to test the logistics of expanding the use of HPV (human papilloma virus) vaccine in girls to prevent cervical cancer, has been castigated by critics for 'unethical human experimentation' – even though the vaccine is hardly experimental – and is now the target of two lawsuits in India.

Publication: The Hindu
Edition: Kochi
Journalist: C. Maya
Date: December 13, 2013
Headline: Pentavalent vaccine caught in fresh row

Synopsis: Even as the Centre is set to scale up use of pentavalent vaccine across the nation, there has been a fresh wave of protests, this time with Leader of the Opposition V.S. Achuthanandan demanding that the "vaccine, which has led to the mass death of infants", be dropped from the government's immunisation programme. Health Department officials say they see no reason why there should be more protests against the vaccine, now that the National Technical Advisory Group on Immunisation (NTAGI), which conducted a study on vaccine-related infant deaths, has recommended to the Union Health Ministry that the vaccine is safe and effective.

Publication: The Hindu
Edition: National
Journalist: Aarti Dhar
Date: December 13, 2013
Headline: Health Ministry worried SC verdict will affect AIDS control

Synopsis: The Health and Family Welfare Ministry has expressed concern over the Supreme Court order that gay sex is illegal, saying the ruling will prevent vulnerable communities from accessing health facilities for fear of discrimination and stigma. "We are concerned that this will discourage people from seeking health care, and consulting with doctors, counsellors and health workers," Ministry Secretary Keshav Desiraju told The Hindu on Thursday. The LGBT (lesbian, gay, bisexual and transgender) is defined as a high-risk group by the National AIDS Control Organisation — now the Department of AIDS Control — with HIV infection prevalence among men having sex with men (MSM) being the highest, between 6.54 and 7.23 per cent. This is the second most vulnerable community after injection drug users.

Innovation

Publication: Mint *(Opinion)*
Edition: National
Journalist: Samar Halarnkar
Date: December 13, 2013
Headline: Old Whine, New Battle

Synopsis: The discovery and disruption of a sensor that allows mosquitoes to hone in on human odours holds great promise. "Earlier this year, I was struck by a mystery mosquito-borne bug whose effects are similar to the painful chikungunya virus. My wrists, fingers and ankles hurt, sometimes forcing me to hobble. The pain has eased over seven months, but there are still many bad days. As a consequence, I find that I am just a little paranoid about mosquitoes. There is good reason for my paranoia. The irksome whine of the mosquito grows louder over the subcontinent. When I was growing up in the Deccan's steamy towns, mosquitoes bit only in the evening. That was the age of the Anopheles, prime carrier of malaria and filariasis—the horror disease of massively swollen legs, also called elephantiasis—and the Culex, whose bites we regarded as harmless because we had never heard of the West Nile fever. Those threats continue, but mosquitoes are now something we fear through the day as well because of the rapid spread of the Aedes species, primarily the aggressive, striped marauder called the Asian tiger mosquito (Aedes aegypti), carrier of dengue fever and chikungunya."

Publication: Pharmabiz
Edition: Online
Journalist: Amiti Sen
Headline: UK Healthcare delegation aims to boost ties with Karnataka

Synopsis: UK Healthcare delegation is now looking to further enhance its ties with the pharma, biotech industry, research centres and hospitals in Karnataka. In this connection, Dr Vince Cable, UK's Secretary of State Minister

for Business, Innovation and Skills, is here in Bengaluru as part of his four-day visit to India. The minister is being accompanied by a healthcare business delegation.