News Updates: December 12, 2013.

Drug Pricing

Publication: The Economic Times
Edition: New Delhi, Online
Date: December 12, 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: The Financial Express
Edition: National
Date: December 12, 2013
Headline: Stockists, retailers have resumed product purchases: GSK Pharma

Synopsis: Drug maker GlaxoSmithKline Pharmaceuticals said stockists and retailers have resumed purchasing its products across the country from the last week of November. The company's sales were affected in the major pockets of the country as stockists and retailers had stopped purchasing its products since September 15. In August, the company had said that a number of its products have come under the Drug Price Control Order (DPCO) 2013, which came into effect in May 2013, resulting in reduction of prices of the company's drugs.

Publication: Business Standard
Edition: National
Date: December 12, 2013
Headline: Justice G S Singhvi: The decision-maker retires

Synopsis: Justice G S Singhvi, known as a bold and pro-active Supreme Court judge who kept government on tenterhooks on public issues, including 2G spectrum scam, retired on Wednesday after delivering his last judgment. Singhvi who used to go minutely into the case files, left unfinished the issue of right to privacy raised by former Tata chief Ratan Tata which arose from the Radia tapes and his tenure also saw many of the other important issues being left undecided. This includes plea on new drug pricing, police reforms and banning gutka.

Publication: The Hindu
Edition: National
Date: December 11, 2013
Headline: GSK Pharma: Product purchases by stockists have resumed

Synopsis: Drug maker GlaxoSmithKline Pharmaceuticals today said stockists and retailers have resumed purchasing its products across the country from the last week of November. The company's sales were affected in the major pockets of the country as stockists and retailers had stopped purchasing its products since September 15. In August, the company had said that a number of its products have come under the Drug Price Control Order (DPCO) 2013, which came into effect in May 2013, resulting in reduction of prices of the company's drugs.

OPPI Mention

Publication: MoneyLife
Edition: Online
Date: December 12, 2013
Headline: ACG Worldwide Brings Global Technology to India With Seminar on Fluid Bed Granulation and Coating

Synopsis: Pam Glatt Pharma Technologies Pvt. Ltd., a Member of ACG Worldwide, Organized a Seminar Featuring Eminent International Speakers at Hyatt, Pune, on 14-15 November, 2013, to Help Pharma Professionals Improve Productivity and Reduce Cost of Manufacturing. ACG Worldwide has been recognized as 'Best Vendor' by OPPI, ACG has also bagged awards for several innovative products from IIP & Pharmexcil. ACG Worldwide serves customers in more than 100 countries and has its subsidiaries in Brazil, China, Europe, Indonesia, North America and Hong Kong.

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

Publication: NDTV Profit
Edition: National
Date: December 11, 2013
Headline: Arvind Kejriwal among Foreign Policy magazine's 100 global thinkers

Synopsis: Aam Aadmi Party's impressive debut in the Delhi elections has earned party founder Arvind Kejriwal a place on Foreign Policy magazine's list of 100 global thinkers "for leading a campaign to clean up India's capital". Anand Grover, a human rights lawyer and the UN special rapporteur on the right to health, makes it "for going to the mat with Big Pharma".

Publication: Zee News
Edition: Online
Date: December 11, 2013
Headline: India Inc strikes deals worth nearly $27 bn in Jan-Nov 2013

Synopsis: India Inc announced mergers and acquisitions deals worth USD 1.31 billion in the month of November, taking the 11-month tally this year to USD 26.76 billion. The month of November witnessed M&A and PE deal activity worth USD 2 billion, which is similar to the levels seen in September and October 2013. Sector-wise, real estate attracted deals worth USD 513.23 million -- the largest percentage of the total deal tally in November (39 per cent), followed by IT & ITeS (USD 225.18 million, 17 per cent), pharma (USD 193.14 million, 15 per cent), banking and financial (USD 175.16 million, 13 per cent) and telecom (USD 80 million, 6 per cent). The top five M&A deals accounted for 63 per cent of the total deal values.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: Mint
Edition: National
Date: December 12, 2013
Headline: CCI orders drug trade body to curb anti-competitive practices

Synopsis: The Competition Commission of India (CCI) has directed the All India Organisation of Chemists and Druggists (AIOCD) to desist from anti-competitive practices that affect the supply of drugs. AIOCD, which has been battling drug companies over better margins for more than two decades, intensified the fight after the introduction of the new drug price control (DPCO) regime that further affected its margins. DPCO was made effective in July, and regulates prices of 348 drugs categorized under the National List of Essential Medicines. Prior to this, prices of only 74 molecules were regulated in India. “We are happy that the drugs have become more accessible to people due to the new DPCO. But pharma companies reduced our margins without any notice,” said Shinde.

Publication: Business Standard
Edition: National

Date: December 11, 2013
Headline: CCI passes 'cease and desist' orders against AIOCD, others

Synopsis: Competition Commission has directed the leading grouping of chemists and druggists, AIOCD, to cease and desist from unfair trade practices that restrict supply of medicines in the market. Finding them in violation of competition norms, the fair trade watchdog has passed orders against All India Organization of Chemists and Druggists (AIOCD) and its affiliates -- All Kerala Chemists & Druggists Association (AKCDA), Assam Drug Dealers Association (ADDA) and Barpeta Drugs Dealers Association (BDDA). Further, the Competition Commission of India (CCI) has slapped penalty of Rs 5.61 lakh on ADDA. Since their financial statements were not immediately available, the regulator said that fine on drug associations of Kerala and Barpeta would decided later at an appropriate time.

Publication: Business Standard
Edition: National
Date: December 12, 2013
Headline: Five Indian cos get FDA nod for anti-depressant drug

Synopsis: Five Indian generic drug makers - Sun Pharmaceuticals, Aurobindo Pharma, Lupin Ltd, Torrent Pharmaceuticals and Dr Reddy's Labs have been given US FDA approval for selling copycat version of blockbuster antidepressant Cymbalta (duloxetine delayed-release capsules). It is one of the most widely prescribed treatments for depression, anxiety and other disorders in the US market. Cymbalta, the fifth largest selling drug in the world, is Eli Lilly's best-selling drug with an annual sales of $4.7 billion. The drug's patent was expired on Wednesday, causing the entry of cheaper generic versions in the US market. Apart from Indian companies, Israel-based Teva Pharmaceuticals has also received the FDA nod.

Publication: The Financial Express
Edition: National
Date: December 12, 2013
Headline: Jubilant's US subsidiary gets USFDA warning over adulteration of drugs

Synopsis: US FDA has said it identified significant violations in the production practices. The US Food and Drug Administration has said it identified significant violations in the production practices at Jubilant Life Sciences' Spokane facility in US, which resulted in the company's drug products to be adulterated. The unit, located in Washington state, operated by Jubilant's US-based subsidiary Jubilant HollisterStier, was inspected by the regulator between April 15 and May 10, 2013. The USFDA said in the letter that it was aware of unexplained increased levels of unspecified impurities in a product, whose name was not stated in the letter. The company has dealt with the issue by withdrawing batches of the product from the market and reducing its expiry date.

Publication: Pharmabiz
Edition: Online
Date: December 12, 2013
Headline: US FDA to issue UFI System for Drug Establishment Registration norms, Indian pharma lauds move

Synopsis: US FDA is expected to issue a guidance on the specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration. The draft of this guidance has been circulated to the industry which has commented and provided their views on the move. Now the regulatory authority is reviewing the industry submissions and is in the process of making adequate efforts to issue the guidance. The Indian pharma industry is upbeat on the guidance. This is because the guidance would ensure total transparency in the operations of the production plant besides indicating the kind of infrastructure in place. This would ensure faster US FDA clearances and easier facility audits.

Publication: Pharmabiz
Edition: Online
Date: December 12, 2013

Headline: Centre finalizing dedicated ASU&H bill with regulatory provisions for herbal extracts, plant-based drugs

Synopsis: Union government is getting ready with the draft of an exclusive bill with regulatory provisions for the Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs. The Ayush industry associations provided their comments on the same, following a communiqué from the Department of Ayush to forward their suggestions on the Bill before November 27, 2013. Now having received the associations' views, the government is ready to finalise the legislation. A dedicated bill was demanded by the industry because of lack of comprehension from the regulatory authority on the Ayush drugs as it came under the Drugs & Cosmetics (D&C) Act. Therefore industry associations were insisting for a separate legislation.

Publication: Pharmabiz
Edition: Online
Date: December 11, 2013
Headline: Pondicherry accounts for highest number of FDCs approved without prior permission from DCGI

Synopsis: Pondicherry, which has been recently in the news regarding violation of 122E Drug & Cosmetic Rules, was found to have approved the highest number of fixed dose combinations without the prior approval of the Drug Controller General of India (DCGI) in the past. According to the information gathered by the Union Health Ministry, of the total 23 such cases of approvals to FDCs, Pondicherry has reported as many as 8 cases. The Centre had fixed October 1, 2012 as the cut-off date for implementing the rule to get prior permission by the state authorities from the DCGI for approving FDCs.

Publication: MoneyLife
Edition: National
Date: December 11, 2013
Headline: China Pharmaceutical Guidebook: (2013 Edition) Latest Chinese Regulations for Imported Drug Registration

Synopsis: China possesses a fourth population in the world and has one of the largest drug markets round the world. By 2012, sales on the Chinese drug market have reached RMB 926.1billion (about US$147 billion) reported by the end of 2012. A series of factors, such as an increasingly ageing population, accelerating growth of the urban population as well as expansion of healthcare covering urban and rural, will grow the Chinese drug market with a growth rate over 20 percent per annum in next three years. China is expected to become the second largest drug market in the world by 2015. Since the reform and open door policy implemented by the Chinese authorities in the late 1970s, the door of the Chinese drug market began opening up to the world step by step, which gave a fillip to the imported drugs from overseas pharmaceutical manufacturers and producers. By 2012, sales of imported drugs have shared one fourth on the Chinese drug market.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Economic Times
Edition: National
Date: December 11, 2013
Headline: Warner Chilcott & Cadila Healthcare settles patent litigation

Synopsis: Ahmedabad-based drug company and India's fifth largest drug maker by revenue, Zydus Cadila Group has settled a patent litigation with US-based Warner Chilcott Company LLC. In a press statement, Zydus Cadila said that Cadila Healthcare Ltd & its US subsidiary Zydus Pharmaceuticals (USA) Inc have entered into an agreement in principle with Warner Chilcott Company LLC to settle all outstanding patent litigation related to Asacol HD (mesalamine) delayed-release tablets. The agreement remains subject to preparation and execution of definitive documentation.

Publication: InfoChange Trade and Development
Edition: Online

Date: December 12, 2013
Headline: Intellectual Property Rights are a privilege, not a human right

Synopsis: Intellectual Property Rights should be subsumed to human rights, national interests and the preservation of genetic resources. The pharmaceutical sector is a classic pointer to the dangers of a strong IPR regime. Large pharmaceutical companies have generated super profits through the patenting of top selling drugs. But drugs that sell in the market may have little to do with the actual health needs of the global population for, often, there is nobody to pay for drugs required to treat diseases in the poorest countries. Research and patenting in pharmaceuticals are driven not so much by actual therapeutic needs, but by the need of companies to maintain their super profits at present levels. Simultaneously, new drug development has become more expensive because of more stringent regulatory laws. This is a major reason for the trend towards global mergers of MNCs. As a consequence, we are looking to a new situation, where 10-12 large transnational conglomerates will survive as 'research based' companies that will be in the business of drug development and patenting. The bulk of drug manufacturing will be done by smaller companies. Given their monopoly over knowledge, these companies will decide the kind of drugs that will be developed, which are likely to be drugs that can be sold to people with the money to buy them. Thus, on one hand, we have the development of 'life-style' drugs, like Viagra, which target the illusory ailments of the rich. On the other hand, we have a large number of 'orphan' drugs, or drugs that can cure life threatening diseases in Asia and Africa , but are not produced because the poor cannot pay for them. Just four per cent of drug research money is devoted to developing new pharmaceuticals specifically for diseases prevalent in developing countries. To put it another way, less than 10% of the $ 56 billion spent each year globally on medical research is aimed at the health problems affecting 90% of the world's population.

Publication: The Free Press Journal
Edition: National
Date: December 11, 2013
Headline: Endo Pharma sues Ranbaxy for patent breach of painkiller

Synopsis: Pennsylvania-based drug maker Endo Pharmaceuticals Inc has sued Ranbaxy Laboratories Ltd and its two US subsidiaries, alleging violation of several patents over pain-management drug Opana ER CRF. According to the suit filed by Endo Pharmaceuticals in the New York district court, Ranbaxy filed an abbreviated new drug application for its generic version of the painkiller with the US Food and Drug Administration in October. Endo Pharmaceuticals is seeking a stay on the launch of generic version of Opana ER CRF by Ranbaxy in the US.

Clinical Trials

Publication: The Hindu
Edition: National
Date: December 12, 2013
Headline: Child-friendly, first-line TB combination drugs will be available in 2016: Dr. Mel Spigelman

Synopsis: Dr. Mel Spigelman, President and Chief Executive Officer of the Global Alliance for TB Drug Development (TB Alliance) is regarded as one of the world's leading experts in tuberculosis and TB drug development. He was instrumental in forging key organisational partnerships and building the pipeline of TB drug candidates when he was the Director of Research & Development at TB Alliance. In an email to R. Prasad, Dr. Spigelman explained the various facets of paediatric TB drug development.
Speaking of the greater involvement by drug companies in producing paediatric TB formulations after UNITAID provided a grant of $16.7 million and USAID also contributed funds, he says that the goal of the grant is to develop first-line TB treatments designed for children, in the proper doses and formulations, but also to help catalyze paediatric TB drug development among pharmaceutical companies through a variety of incentives. More accurately defining the market, clarifying the regulatory pathways for new products, and addressing barriers to entry for manufacturers are all within the scope of our work, and will help bring new partners into the field. How long would it take to come up with fixed-dose combination drugs for first-line TB drugs? How long would a clinical trial take and how many subjects are needed to test bioavailability? One of the significant challenges to the development of new paediatric TB treatments is the need for additional clarity on what is needed for such a product to receive approval by the various regulatory authorities around the world. These studies can take 6 to 18 months to complete. The quantity and scope of these studies required for regulatory approval can vary by country. We are working to collect that information and disseminate it widely, so that those with the capacity to

work in this space have a clear understanding of what needs to be done, how to do it, and what regulators need to see to make approval decisions.

Publication: Pharmabiz
Edition: Online
Date: December 12, 2013
Headline: ICMR, CCRUM enter research & training pact to provide manpower training in preclinical & clinical research

Synopsis: The Central Council for Research in Unani Medicine (CCRUM) has entered into a research and training agreement with the Indian Council of Medical Research (ICMR) under which the ICMR will provide manpower training in several areas related to preclinical and clinical research especially clinical trials carried out under the Unani system as well as to bring in factor of quality to existing research practices presently operative.

General Industry

Publication: The Economic Times
Edition: National
Journalist: Preeti Kulkarni
Date: December 12, 2013
Headline: Health insurance: Should one go for disease-specific cover or a regular policy

Synopsis: Insurance companies are gradually warming up to the idea of offering specially-designed health insurance policies to individuals with health conditions such as diabetes and hypertension, among others. Recently, standalone health insurer Apollo Munich launched a health insurance plan specifically targeted at individuals suffering from diabetes and hypertension, among other conditions**.**

Publication: Mint
Edition: National
Date: December 12, 2013
Headline: Dr Reddy's targets to sell copy of Roche's Rituxan in Europe

Synopsis: Dr Reddy's Laboratories Ltd, 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's Rituxan, in Europe. "A partnership the Hyderabad-based company struck with Merck KGaA'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 Times of India
Edition: National
Journalist: Manoj Mitta
Date: December 12, 2013
Headline: There's Room for Review

Synopsis: The last time the Supreme Court hit global headlines was in the Novartis case in April when it raised the bar for patents and made a life saving drug more accessible to cancer patients. The reason this time for making waves around the world could not have been worse. Among the repercussions of its ruling on Wednesday in the Section 377 case is that HIV/AIDS patients among LGBT persons may not any longer be able to access public health facilities without running the risk of being harassed or even arrested.

Publication: The Hindu
Edition: National
Date: December 11, 2013
Headline: EU fines Novartis, J&J for delaying generic painkiller

Synopsis: The European Union is fining pharmaceutical giants Novartis and Johnson & Johnson a total of 16 million euros ($22 million) for delaying the launch of a generic painkiller in the Netherlands, the bloc's executive announced on Tuesday. The drug in question is a cheaper version of Fentanyl, a painkiller that is 100 times more potent than morphine and is notably used by cancer patients, according to the European Commission. "The two companies shockingly deprived patients in the Netherlands, including people suffering from cancer, from access to a cheaper version of this medicine," said EU Competition Commissioner Joaquin Almunia.

Publication: NDTV Profit
Edition: National
Date: December 11, 2013
Headline: How to choose the best critical illness cover

Synopsis: Critical illness cover, also referred to as critical illness insurance, is an insurance policy where you'll get a tax-free 'lump sum' - a one-off payment - if you're diagnosed with one of the serious illnesses covered by your insurance policy. Every insurance policy has some clauses and limitations attached to it. Similarly, a critical illness insurance policy has its own restrictions. For example, a critical illness plan may not cover all chronic diseases/illnesses; such as -
a) Any critical illness arising out of any genetic illness or disorder
b) Any critical illness due to alcohol, smoking, other tobacco intake or drug abuse
c) Critical illness acquired because of Human Immune-deficiency Virus (HIV) infection
d) Critical illness arising due to intentional self-injury, suicide or attempted suicide

Publication: Pharmabiz
Edition: Online
Date: December 12, 2013
Headline: Nearly 5000 delegates expected to take part in 65th IPC starting from Dec 20 in Delhi

Synopsis: As the preparations nearing completion for the 65th edition of the Indian Pharmaceutical Congress (IPC), the organisers are looking for a large turnout of delegates and strong presence of regulatory officials in the mega event that brings together all stakeholders of pharma and allied industries. Around 5000 delegates are expected and there was a huge response to the call for papers and posters already. The presence of top officials from the Union Government and the States will be a major attraction of the event, said A K Nasa, president of the Indian Pharmaceutical Congress Association (IPCA) which is organising the meet.

Publication: Business Standard
Edition: National
Date: December 12, 2013
Headline: Excellence unlimited: BS jury selects the best 5

Synopsis: The jury said Sun Pharmaceutical had not only changed the landscape of the Indian pharmaceutical industry but also set new standards. Led by Dilip S Shanghvi, Sun Pharma has grown at a stupendous rate in the past couple of years, partly aided by acquisitions at attractive valuations. Its net sales have grown at an annual rate of over 40 per cent in the past three years, whereas its profit growth was 37 per cent.

Innovation

Publication: The Economic Times
Edition: National
Date: December 12, 2013
Headline: G8 aims to beat dementia by 2025 with AIDS-style fight

Synopsis: Leading countries set a goal of finding a cure or effective treatment for dementia by 2025 on Wednesday and ministers said the world needed to fight the spread of the memory-robbing condition just as it fought AIDS. The move by the Group of Eight (G8) nations matches the date set by the United States last year for

beating Alzheimer's - but the target is ambitious, considering there is no obvious cure on the horizon. The health ministers also agreed to appoint a global envoy for dementia innovation, following a template used for HIV and climate change.

Access and Affordability

Publication: Mint
Edition: National
Date: December 11, 2013
Headline: Healthcare policy: Affordable, and for everyone

Synopsis: A hybrid model will keep the execution of a national healthcare policy within budget. Universal health coverage (UHC) has become an important aspect of public policy world over. Some countries have experimented with demand side financing and other interventions in addition to traditional supply side mechanisms funded by taxes with some success. Low levels of government spending in India (about 1.1% of gross domestic product, or GDP and 31% of total healthcare spending) has led to high levels of private spending and out-of-pocket expenditure. Recent pronouncements in the draft 12th Five Year Plan to increase government spending on healthcare to 3% of GDP and to roll out UHC means having a structure that ensures affordable and quality health services to all Indians. The 7th Health Insurance Summit 2013 organized by the Confederation of Indian Industries.

Publication: The Times of India
Edition: National
Date: December 12, 2013
Headline: Drive to contain HIV among high-risk communities could be in jeopardy

Synopsis: The government's health programmes targeting high-risk communities to contain HIV prevalence could be in jeopardy after the Supreme Court order criminalizing homosexuality. Naz Foundation executive director, Anjali Gopalan, said access to health and educational facilities were bound to be impacted adversely.