News Updates: November 12, 2013

Key Highlights

Patents–

- **Hindustan Times** published a report highlighting that the pharmaceutical industry as a whole is facing a number of significant challenges, including a wave of expiring patents and deep spending cuts in many public health sectors, forcing companies like Novartis to restructure and slim down.

Post Marketing Surveillance of Drugs –

- **Pharmabiz** published a report stating that the Health Ministry is planning to make the post-marketing surveillance of drugs mandatory for six years, instead of the current practice of four years, under the Schedule Y provisions of the Drugs and Cosmetic (D&C) Rules. The move comes in accordance with the recommendations by the Prof Ranjit Roy Chaudhury expert committee.

Intellectual Property Rights –

- In the **New Indian Express**, CBI Director Ranjit Sinha is quoted saying "Violation of intellectual property rights is a subject of growing relevance for corporates, governments and other stakeholders"

Drug pricing –

- **The Economic Times** quotes Sharan Prakash R Patil, Medical education minister speaking of setting up a new corporation to extend drugs to patients undergoing treatment in government facilities and procure drugs in bulk at cheaper prices from pharmaceutical company and extend it free to the patients.

Clinical Research / Trials

Publication: The Hindu *(Reproduced from PTI)*
Edition: National
Date: November 12, 2013
Headline: SC issues notice to Centre, PATH on clinical trials

Synopsis: The Supreme Court on Monday issued notice to the Program for Appropriate Technology in Health (PATH), an international NGO working in the health sector, on a PIL alleging that it indulged in unethical conduct of clinical trials in collaboration with ICMR between 2009-10 in Andhra Pradesh and Gujarat. The petitioner alleged that there were serious failures on the part of PATH and Indian Council of Medical Research (ICMR) in complying with legal and ethical requirements to obtain written 'informed' consent and it caused serious adverse events. Earlier, a bench headed by Justice R.M. Lodha, which was hearing a batch of PILs against clinical trials, had said that trials in the country must be held to help people here and must not be allowed for the benefits of multinational companies.

Publication: Mint
Edition: National
Date: November 12, 2013
Headline: Suven Life Sciences reports sixfold rise in Q2 net

Synopsis: Hyderabad-based biopharmaceutical company Suven Life Sciences Ltd on Monday reported a sixfold increase of net profit in the three months ended 30 September on account of higher sales from its contract research and manufacturing services (CRAMS) business. Suven's new chemical entity for dementia, SUVN-502, entered phase 1b clinical trial in the US, the company said. The company has been trying to find a partner who will further develop the molecule.

Publication: The Indian Express

Edition: National
Date: November 12, 2013
Headline: To develop dengue vaccine, Serum institute ties up with Thailand univ

Synopsis: Reasearchers at the Serum Institute of India have taken up the challenge of developing a vaccine against dengue virus. In its efforts, researchers here have tied up the University of Mahidol, Thailand. Till October, India has reported 55,063 dengue cases and 138 deaths. Adding to the ongoing efforts is Serum Institute's move to join hands with researchers in Thailand. Dr Rajeev Dhere, Executive Director, Serum Institute of India Limited, said four seeds of the dengue serotypes have been developed by researchers at Thailand. It will still take some time before we can commence clinical trials, Dhere said.

Publication: Pharmabiz
Edition: Online
Date: November 12, 2013
Headline: Health Min plans to make post-marketing surveillance mandatory for 6 years

Synopsis: The Health Ministry is planning to make the post-marketing surveillance of drugs mandatory for six years, instead of the current practice of four years, under the Schedule Y provisions of the Drugs and Cosmetic (D&C) Rules. The D&C Rules will thus be amended to make it mandatory for six years for all drugs permitted to be marketed in India. The move comes in accordance with the recommendations by the Prof Ranjit Roy Chaudhury expert committee. Among several recommendations to streamline the clinical trials sector, the panel had suggested creation of a detailed protocol to monitor and record the side-effects and efficacy of the drugs. The focus of a PMS study should be to monitor hitherto-identified risks, potential risks and missing information, the panel said.

Patents / Compulsory Licensing / Intellectual Property Rights

Publication: Hindustan Times
Edition: National
Date: November 12, 2013
Headline: Novartis sells blood transfusion test unit for $1.7 bn

Synopsis: Swiss pharmaceuticals giant Novartis said on Monday it would sell its blood transfusion diagnostics unit to the Spanish firm Grifols for $1.68 billion (1.25 billion euros), with analysts saying more divestments could lay in store. The pharmaceutical industry as a whole is facing a number of significant challenges, including a wave of expiring patents and deep spending cuts in many public health sectors, forcing companies like Novartis to restructure and slim down.

Publication: The New Indian Express
Edition: National
Date: November 12, 2013
Headline: Decisions by policy makers should have no scope for impropriety: CBI Chief

Synopsis: CBI Director Ranjit Sinha said “Violation of intellectual property rights is a subject of growing relevance for corporates, governments and other stakeholders”. Giving details of future roadmap for the agency, Sinha said agreement is underway with the National Institute of Mental Health and Neurological Sciences, Bangalore for interactive partnership in forensic psychiatry and development of scientific interrogation techniques.

Drug Pricing / Trade margins

Publication: The Economic Times
Edition: National
Date: November 12, 2013

Headline: Mideast, Africa drug importers seek discounts after price cuts in India

Synopsis: Many small and medium drugmakers are under pressure from buyers in key foreign markets to cut prices, in line with government-mandated price reductions in India. In May, the government's Drug Price Control Order set price caps on 151 of 348 "essential" medicines amid resistance from the industry. Now importers in the Gulf region as well as some African nations are demanding that they be given drugs at reduced prices too. As a result, many small and medium Indian drugmakers are finding it difficult to execute export orders. India exported medicines worth $1 billion (about Rs 6,300 crore) to the Gulf and over $2.6 billion (Rs 16,400 crore) to the African region in 2012-13.

Publication: The Economic Times
Edition: National
Date: November 12, 2013
Headline: Aurobindo at a record high, price-to-earnings at 32% discount to peers

Synopsis: Aurobindo Pharma continues to be a bargain in the pharmaceutical space despite the stock hitting a new lifetime high on Monday. Aurobindo Pharma has entered into high-margin therapies like oncology, hormone and differentiated products like peptides, with the recent acquisitions of Celon Laboratories and Silicon Life Sciences. Analysts say Aurobindo Pharma has witnessed consistent improvement on its revenue and operating margin fronts over the last six quarters, driven by resolution of US FDA compliance issues, better product mix and less focus on low margin drugs.

Publication: The Times of India
Edition: National
Date: November 12, 2013
Headline: Government plans to purchase generic drugs directly from pharma company

Synopsis: The medical education minister Sharan Prakash R Patil on Monday said a committee has been formed to study the best practices available in other states to extend drugs to the patients undergoing treatment in government facilities. The aim of the move is to procure drugs at cheaper prices and extend it free to the patients. There is a proposal to set up a new corporation to procure drugs in bulk. The drug suppliers will be kept out of it. The proposed corporation will directly deal with the pharmaceutical company and purchase the drugs, he stated.

Publication: The Financial Express
Edition: National
Date: November 12, 2013
Headline: Drugs prices control a step in the right direction

Synopsis: Focusing on pharmaceutical innovation funded by revenue from generics, Glenn Saldanha, the 44-year-old CEO of Mumbai-based Glenmark Pharmaceuticals Limited, stands apart from his peers. A firm supporter of the government's drug-pricing policy, Saldanha tells Pallavi Ail that despite foreign health regulators mounting scrutiny on Indian manufacturing plants, ANDA approvals show that US still relies upon India for its generic drugs. The new drugs prices control policy is a step in the right direction. If you look across emerging markets, pricing policy is common and the regulator always tries to strike a balance between the needs of society and create a platform for a healthy generic industry. The pricing policy is quite well-balanced in that regard and a lot of thought and deliberations have gone into it prior to implementation. The list of products that are under the National List of Essential Medicines (NLEM) constitute over 50% by volume of the total market, and thus a large portion of the industry is now under price control.

Publication: Financial Chronicle
Edition: National

Date: November 12, 2013
Headline: GSK Pharma's profit tumbles amid drug price row

Synopsis: GlaxoSmithKline Pharmaceuticals, the Indian unit of British drugmaker GSK Plc, reported a 33.7 per cent drop in profit for the third quarter ended September 30 due to decreased domestic sales. The uncertainty in pricing among the distribution channel and revised drug prices resulted in the drop in sales. "The quarter saw the impact of the introduction of the revamped Price Control Order, extending coverage to the National List of Essential Medicines (NLEM). The quarter was also impacted by a segment of the trade not buying the company's products and supply constraints," the company said in a release. GSK offers a number of medicines whose prices are controlled by the government.

FDI

Publication: Business Today
Edition: Online
Date: November 12, 2013
Headline: India Inc's January-October deal tally falls 17 per cent to $25.8 bn

Synopsis: India Inc's margers and acquisition (M&A) activity in the first 10 months of this year remained muted, with just 411 deals amounting to $25.48 billion, registering a decline of 17 per cent from the same period a year ago. Major deals announced in October include Bupa Care services' acquisition of Quality Healthcare Medical Services for $355 million, followed by Jubilant Pharma's 100 per cent stake acquisition in Jubilant Life Sciences' active pharmaceutical ingredient and dosage's business for $185 million.

FDA

Publication: Business Standard
Edition: National
Date: November 11, 2013
Headline: Ranbaxy vs Singh brothers: The consumers are the real losers

Synopsis: The fight between Japanese pharmaceutical company Daiichi Sankyo and the erstwhile owners of Ranbaxy, Malvinder Singh and Shivinder Singh has entered a new phase. The Japanese company has accused the two of concealing and misrepresenting facts at the time of its $2.4 billion purchase of the company in 2008. More than the money involved, it is the reputation of the company that has taken a beating. On at least 15 of Ranbaxy's new drug applications, the USFDA found over 1,600 data errors. These are bioequivalence figures which are needed to prove a generic is at least an 80% chemical match of the branded drug – either did not exist or were fabricated. This has put Ranbaxy on a sticky wicket. Ex-employees in the US have been quoted in the US media (CBS interviewed Dr. Kathy Spreen who was hired by Ranbaxy in 2004 to help Ranbaxy comply with FDA regulation) as saying they found data fabrication way back in 2004 and even when it was brought to the notice of Malvinder Singh, nothing was done about it.

Publication: Business Standard
Edition: National
Date: November 12, 2013
Headline: Daiichi drags Malvinder to Singapore court

Synopsis: Daiichi Sankyo, the Japanese parent of Ranbaxy Laboratories, has dragged the latter's previous promoter Malvinder Mohan Singh to a court in Singapore for concealing and misrepresenting critical information relating to the US Food and Drug Administration (FDA) and Department of Justice (DoJ) investigations at the time of the purchase, sources say. Industry observers say the litigation between the current owners of Ranbaxy and its former promoters is likely to be stretched and might become a major corporate war. Daiichi Sankyo is a big international player and if they are feeling cheated, they will not let it go so easily. Ranbaxy was one of the costliest deals of the time and Daiichi had to pay a hefty penalty of $500 million for what they believe were misdeeds of the past. The reputation damage is over and above all this,

says a pharma industry veteran.

Publication: Business Standard
Edition: National
Date: November 12, 2013
Headline: Lupin: Aciphex launch to reduce near-term concerns

Synopsis: Lupin has announced the launch of Aciphex (generic version) delayed-release tablet 20 mg in the US market. The Eisai Inc's brand Aciphex containing Rabeprazole, a drug used for treatment of gastric disorders, had clocked in $864 million in July 2012 – June 2013, as per IMS data. Post today's launch, Lupin has already launched 11 products in the US market this year and received 15 approvals. Cumulative ANDA filings for the company with the US FDA now stand at 183 with 92 approvals to date.

Publication: Business Standard
Edition: National
Date: November 12, 2013
Headline: Aurobindo Pharma: Out of the woods

Synopsis: After the resolution of all US Food and Drug Administration (FDA)-related issues, Aurobindo's US growth was expected to be strong, led by the re-launch of cephalosporins (anti-bacterial class of drugs) from unit-VI and market share gains by abbreviated new drug applications (ANDAs) launched during the last 12 months. But the company surprised many with a performance that beat Street expectations. Owing to the upbeat performance and improving revenue growth visibility, analysts are now upgrading their earnings estimates and target prices for the company.

Publication: Mumbai Mirror
Edition: National
Date: November 12, 2013
Headline: Chemists rush to reopen shops after FDA invokes essential services act

Synopsis: A majority of chemists who took part in a day-long strike on Monday re-opened their shops prematurely after the Food and Drug Administration (FDA) called in drug inspectors from Thane to penalise the participants under the Maharashtra Essential Services Maintenance Act (ESMA).

Publication: Mumbai Mirror
Edition: National
Date: November 12, 2013
Headline: Doc sparks alert on TB drug with wrong dosage

Synopsis: Dr Kartik Shah reports the matter to FDA after a patient takes ill, vomiting repeatedly for five days and complaining of severe stomach ache. A south Mumbai doctor has written to the Food and Drug Administration seeking withdrawal of pharma major Sandoz's tuberculosis combination drug '4D' from the market after he found some of its strips carrying wrong, potentially damaging dosage.

Publication: The Hindu
Edition: National
Date: November 11, 2013
Headline: Biocon academy to offer training in biotechnology

Synopsis: Concerned over the lack of industry-ready graduates in the biotech sector, Biocon has launched its own academy. To address this, Biocon's academy will offer modules on introduction to US FDA and European

laws, molecular biotechnology, pharmaceutical development, biopharmaceutical quality assurance and control, CMC regulations of pharmaceuticals, mammalian cell biotechnology, fermentation principles, bioseparation engineering & science and professional skills development.

Publication: The Telegraph India
Edition: National
Date: November 12, 2013
Headline: Wockhardt eyes listing in Europe

Synopsis: Drug maker Wockhardt plans to list its overseas holding arm — Wockhardt Bio AG — in Europe. It's rare for Indian drug companies to list overseas. Ranbaxy Laboratories and Dr Reddy's Laboratories are the only two Indian drug makers to have done so. Interestingly, the plan to list its overseas holding company comes at a time Wockhardt has been facing regulatory scrutiny for some of its plants here in the country. In May, the US FDA had issued an import alert against the Waluj facility, which makes injectables and solid dosages. Subsequently, the Medicines and Healthcare Products Regulatory Agency, the drug regulator in the UK, withdrew its GMP (good manufacturing practice) certificate issued to the company's manufacturing facility at Kadaiya in Gujarat. The regulator also withdrew the good manufacturing certification granted to the Chikalthana facility in Maharashtra.

Publication: Pharmabiz
Edition: Online
Date: November 12, 2013
Headline: US FDA issued norms on bioanalytical method, industry to comment before December end

Synopsis: US FDA has issued a draft guidance on the Bioanalytical Method Validation. The rules provide assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and supplements. The guidance is for developing bioanalytical method validation information used in human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies that require pharmacokinetic (PK) or biomarker concentration evaluation.

Publication: Pharmabiz
Edition: Online
Date: November 12, 2013
Headline: RDCA to stop dispensing medicines without prescription in response to FDA diktat

Synopsis: The joint coordination committee of the Retail and Dispensing Chemists Association (RDCA) and Pharmaceutical Wholesalers Association (PWA) are planning to stop the practice of dispensing medicines to the patients who approach chemist shops without having a doctor's prescription. There are 7000 pharmacies in the city and all of them downed shutters today against Maharashtra Food and Drug Administration's (FDA) tough stance against enforcing rules on chemist shops.

Drug Regulatory

Publication: The Economic Times
Page no: 6
Journalist: Soma Das
Headline: DGCI Turns Down Puducherry Drug Firm's Application

Synopsis: The firm GuruFcure has been accused of fabricating data while seeking nod for making seven combination drugs. As per the company's website, its clients include leading pharma companies such as Abbott, Alkem, Glenmark, Wockhardt etc.

Publication: The Hindu Business Line
Edition: National
Date: November 12, 2013
Headline: Ranbaxy battle: Regulatory woes and sparring promoters

Synopsis: Five years after the Ranbaxy promoter-family, the late Parvinder Singh's sons Malvinder and Shivinder Singh, sold their entire stake in the Indian drug-maker to Japanese major Daiichi Sankyo, the story refuses to die down. There has scarcely been a dull moment, what with repeated raps from the USFDA, a whistle-blower and now reports of arbitration. Ranbaxy's erstwhile promoters had wowed India Inc by pulling off a $4-billion sale even as the economic downturn unfolded in 2008. But that is all in the past.