News Updates: December 20, 2013

FDI/ Foreign Investment in Pharma

Publication: The Economic Times
Edition: National
Date: December 20, 2013
Headline: After Tesco-Tata Deal, Anand Sharma hopes more retail majors to set up in India

Synopsis: Commerce and Industry Minister Anand Sharma expects other major global retailers to invest in India after Tesco announced $110 million investment in the multi-brand retail sector in partnership with Tatas. Sharma was speaking to reporters after a meeting with George Nakayama, president and CEO of Daiichi Sankyo, Japan. Surely, there is benefit for the investors and it is very clear that when others identify their domestic partners or Indian partners, they will come soon, he added. On foreign direct investment in the pharma industry, Sharma said the government would not change FDI cap in the sector. "We are very clear that when it comes to both the greenfield and brownfield, 100% FDI is allowed. We are not changing, in any case," Sharma said.

Publication: The Financial Express *(Reproduced from PTI)*
Edition: National
Date: December 19, 2013
Headline: Blackstone to sell Emcure Pharmaceuticals stake to Bain Capital

Synopsis: Private equity major Blackstone is selling its stake in Pune-based Emcure Pharmaceuticals to Bain Capital. However, the transaction is subject to regulatory approvals including from the Foreign Investment Promotion Board (FIPB), the release said. Talking about the development, Blackstone's co-head of private equity Amit Dixit said, "Emcure was the first private equity investment by Blackstone in India. Since our investment, the company has significantly strengthened its position in the Indian pharmaceutical market and established a strong presence in the US and other semi-regulated markets."

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: BusinessWire India
Edition: National
Date: December 19, 2013
Headline: IP Fame Joins Hands with Lex Witness for the IP Leadership Forum 2014

Synopsis: New Delhi is set to witness a comprehensive discussion and thought-provoking dialogue on Intellectual property (IP) challenges being faced by diverse sectors in today's turbulent milieu at The IP Leadership Forum 2014 (www.eventipr.com) from 7th to 9th January 2014 at Hotel Le Meridien. The convention is an initiative of IP Fame - A company catering to awareness on intellectual property throughout the country, in association with Lex Witness – India's first Magazine on Legal and Corporate Affairs.

FDA / Drug Regulatory / DCGI / Drug Policy

Publication: The Economic Times
Edition: National
Date: December 20, 2013
Headline: Daiichi may get Japanese experts to help Ranbaxy meet USFDA quality

Synopsis: Ranbaxy Labs' parent company Daiichi Sankyo may bring in additional teams of technical experts from Japan to help the former meet quality concerns raised by US Food and Drug Administration (FDA). Daiichi President and CEO George Nakayama, who met Commerce and Industry Minister Anand Sharma on Thursday during his visit to India is understood to have given assurance about augmenting quality measures in Ranbaxy's

existing plants in India and taking corrective measures to ensure full compliance to US prescribed regulatory norms.

Publication: The Times of India
Edition: National
Date: December 20, 2013
Headline: This drug testing lab requires no staff

Synopsis: Chief minister Oommen Chandy along with his cabinet colleagues K Babu, V S Sivakumar and MLA Benny Behannan threw open the Rs 10-crore Regional Drugs Testing Laboratory at Kakkanad on Monday even before completing the recruitment of staff to run the institution. The laboratory, which has infrastructure to test around 10,000 samples a year, requires a staff of 150. At the time of inauguration, the government has allotted only 30 officials, including a deputy government drug analyst, which will affect its functioning. Even these postings are not permanent as the Public Service Commission (PSC) has not yet prepared the rank list of drug analysts, key to running the facility.

Publication: The Times of India
Edition: National
Date: December 20, 2013
Headline: Chemists can file online application to get licences

Synopsis: The Nashik divisional office of the Food and Drug Administration's (FDA) drug division has gone online for registering chemist shops and pharmacists. The applications to get licences to open medical shops can now be submitted online. Speaking to TOI, Ramesh Urunkar, officiating joint commissioner (drug), Nashik division of FDA, said, "We have started online facility to file applications to get licences for opening new chemist shops. The chemists need not come to the office of the FDA to submit applications, which can be submitted online from anywhere.

Publication: The Times of India
Edition: National
Date: December 19, 2013
Headline: Health dept cites 1998 order to revoke ban on vaccines

Synopsis: The health department on Wednesday lifted a ban on supply of pentavalent vaccine ampoules without the manufacturing date in the state, imposed by the minister following the TOI expose, by quoting a 1998 order from the drugs controller general of India. This newspaper had reported the violation of the Drugs and Cosmetics Act in the supply of vaccines without manufacturing dates to hospitals. Additional director of health services Dr N Sreedhar, who is in charge of the immunisation programme, said the ban was lifted after they found that there was an exemption given to the manufactures of pentavalent vaccine by the drugs controller general of India. "There is an exemption given by the drugs controller general of India (DCGI) to the Serum Institute of India from using the manufacturing date. Hence, we ordered that there was no need for stopping the vaccination programme," he said.

Publication: Business Standard
Edition: National
Date: December 19, 2013
Headline: Wockhardt: Too early to rejoice

Synopsis: While the listing of its subsidiary will rub off positively on valuations, resolving of US FDA issues is crucial and not expected soon

Publication: Business Standard
Edition: National

Date: December 19, 2013
Headline: AstraZeneca pays USD 4.1 billion for diabetes buyout

Synopsis: Anglo-Swedish drugmaker AstraZeneca PLC will buy out Bristol-Myers Squibb Co's stake in their partnership to develop and sell diabetes drugs in a deal worth USD 4.1 billion seizing an opportunity to serve the projected explosion of patients suffering from the disease.

Publication: Business Standard
Edition: National
Date: December 19, 2013
Headline: Ranbaxy officials meet Anand Sharma

Synopsis: Even as drug maker Ranbaxy Laboratories is struggling to resolve manufacturing related issues with the US drug regulator and resume supplies to the market from its Indian facilities, senior officials of the company along with Joji Nakayama, Chief Executive of its Japanese parent Daiichi Sankyo, met commerce minister Anand Sharma on Thursday afternoon. The officials discussed various issues including concerns raised by the US Food and Drug Administration and Daiichi Sankyo's India strategy, a commerce ministry official said.

Publication: The Hindu Business Line
Edition: National
Date: December 19, 2013
Headline: Wockhardt's Swiss arm to list in Berne exchange

Synopsis: Drug-maker Wockhardt Ltd on Thursday said it is scheduled to list on the Berne Stock Exchange, Switzerland. The development comes even as the company received an import alert from the US Food and Drug Administration late last week, on its veterinary products, from its Chikalthana and Waluj units in Maharashtra. Incidentally, these units already face an import ban on products supplied from them to the US.

Publication: The Hindu
Edition: National
Date: December 19, 2013
Headline: Panel for professionally-managed Central Drugs Administration

Synopsis: Rejecting the proposal of the Ministry of Health and Family Welfare to set up a Central Drugs Authority, to check malpractices in drug manufacturing, a Parliamentary panel has, instead, recommended creation of a professionally-managed Central Drugs Administration under the amended Drugs and Cosmetics Act. In its 79th report on the Drugs and Cosmetics (Amendment) Bill, 2013, the Parliamentary Standing Committee on Health and Family Welfare has said that there was a need for effective discharge of enforcement activities, which requires a strong, professionally-managed administration that can take action against unscrupulous manufacturing companies.

Publication: MoneyControl
Edition: Online
Date: December 19, 2013
Headline: Daichii plans to bring in technical experts to help Ranbaxy

Synopsis: Japanese drug maker Daichii Sankyo is planning to bring in technical people and expertise to help its Indian arm Ranbaxy comply with USFDA requirements, after repeated failures in compliance.

Publication: Pharmabiz
Edition: Online
Date: December 20, 2013
Headline: CDA formation, DPCO, dual control over pharmacy education to dominate IPC discussions

Synopsis: The Indian Pharmaceutical Congress (IPC) will make a strong pitch for leaving the control of pharmacy education exclusively to the Pharmacy Council of India (PCI), instead of the present system of dual control maintained also by the All India Council for Technical Education (AICTE).

Publication: Pharmabiz
Edition: Online
Date: December 19, 2013
Headline: Indegene & DrugLogic to offer full lifecycle drug monitoring with interactions & safety info

Synopsis: Indegene and DrugLogic have now teamed up to jointly offer for pharmaceutical companies and healthcare organisations a sophisticated Big-Data analysis capability with Qscan. This offering combines sophisticated evidence-based statistical results, with experience-based physician monitoring, to help decipher a drug's clinical behaviour and detect signals related to its safety and interactions with other factors.

Drug Pricing / Price Control

Publication: Press Information Bureau
Edition: National
Date: December 19, 2013
Headline: Endeavour for Reaching Cheaper Medicines to the Poor Continues Through 2013 **– Year End Review**

Synopsis: The new Drug Price Control Order (DPCO) 2013 came into being w.e.f 15th May, 2013. Under the new DPCO 2013 the prices of 348 drugs covering around 652 formulations have been brought under price control. As per the provisions of DPCO, 2013 prices are now being fixed based on the average Price to the Retailer (PTR) of the medicine having market share more than or equal to one percent of the total market turnover adding 16% margin to retailer thereto. All the previous DPCOs, 1970, 1979, 1987 and 1995 were based on cost to manufacturers with post manufacturing expenses.

Publication: The Times of India
Edition: National
Date: December 19, 2013
Headline: Make laws that favour growth of private sector healthcare: Indian Medical Association

Synopsis: The laws in the country do not favour the right growth of private sector healthcare, believes secretary general of Indian Medical Association (IMA) Dr Narendra Kumar Saini. He made a case against two such laws; the need to display prices of all medical procedures by all health care providers under the much debated Clinical Establishment Act and the equally hot topic of generic drugs. "Price control in terms of services offered by a hospital is impractical and unrealistic. At the most, we can provide patients with a list of minimum amounts for different procedures as things are different for every patient undergoing the same procedure. Medical science is not based on set formulas or patterns. If it can be proven to be viable for government hospitals, we will also start using the same," he said.

Publication: Team Invntree
Edition: Online
Date: December 19, 2013
Headline: Two angles to compulsory licensing of patents and a disaster waiting to happen

Synopsis: One of the core objectives of a patent system is to make the patented technology available to the public at reasonably affordable price, meet the reasonable requirements of the public and should be worked in the territory of India. A compulsory license will be granted on a patent only if the patent holder uses his patent in a manner that contravenes the aforesaid objective.

Clinical Trials

Publication: Mint
Edition: National
Date: December 19, 2013
Headline: Bayer to buy cancer-drug partner Algeta for $2.9 billion

Synopsis: Bayer AG agreed to buy Algeta ASA, its partner on a prostate-cancer medicine, for about 17.6 billion kroner ($2.9 billion), to gain control of the drug and experimental radiation therapies. Bayer will begin an offer to buy Algeta shares at 362 kroner each, the Leverkusen, Germany-based company said in a statement on Thursday. Algeta said last month it had received a preliminary offer from Bayer for 336 kroner. New medicines such as Xofigo, the prostate-cancer drug, will help Bayer grow as earnings lag at its plastics division, the company has said. Bayer is funding some clinical trials for Xofigo, and buying Algeta would mean it doesn't need to share profits or pay royalties on the medicine.

Publication: The Economic Times *(Reproduced from Reuters)*
Edition: National
Date: December 19, 2013
Headline: Sanofi to tap ACC registry for cardiovascular clinical trial

Synopsis: French drugmaker Sanofi and its US partner Regeneron are collaborating with the American College of Cardiology (ACC) to identify patients for clinical trials on alirocumab, their new cholesterol treatment and potential blockbuster. Under this agreement, the ACC will use its expertise in clinical research and its extensive patient registries to identify appropriate candidates for a cardiovascular outcomes clinical trial, Sanofi said in a statement on Thursday.

Publication: The Hindu
Edition: National
Date: December 19, 2013
Headline: Panel for professionally-managed Central Drugs Administration

Synopsis: Rejecting the proposal of the Ministry of Health and Family Welfare to set up a Central Drugs Authority, to check malpractices in drug manufacturing, a Parliamentary panel has, instead, recommended creation of a professionally-managed Central Drugs Administration under the amended Drugs and Cosmetics Act. The Committee said that the central drugs administration should be headed by a chief drug controller general of India of the rank of secretary/special secretary who possesses the requisite technical and professional expertise for the role. The panel also said that the chief controller general should be selected by a committee headed by the Cabinet Secretary with the review of the functioning of CDA to be done by a panel of independent experts under the Act. There should be three separate sections dealing with clinical trials, cosmetics and medical technologies, the panel noted.

Publication: Daily News and Analysis
Edition: National
Date: December 20, 2013
Headline: Twin US studies unlock mystery of how HIV causes AIDS

Synopsis: US scientists have discovered the basic mechanisms that allow HIV to wipe out the body's immune system and cause AIDS, which could lead to new approaches to treatment and research for a cure for the disease that affects 35 million people around the world. In the paper published in Nature, the team explored the implications of blocking this cellular suicide with experiments using anti-inflammatory drugs that block the caspase-1 enzyme, including the Vertex drug VX-765. Greene said the company tested the treatment in patients with a chronic seizure disorder who would not respond to normal anti-epileptics, but the effect was not strong enough to continue development. What they did find in a six-week clinical trial in people is that the drug was safe and well-tolerated. "We would like to see if that drug could be repurposed to prevent inflammation in CD4 T cell loss in HIV infection," Greene said.

Publication: Pharmabiz
Edition: Online
Date: December 20, 2013
Headline: Centre planning to form 3 member Central Accreditation Council for clinical trials

Synopsis: Union government is working to form a three member Central Accreditation Council for clinical trials under the chairmanship of Dr YK Gupta, national scientific co-ordinator, Pharmacovigilance of India (PvPI). The Council would oversee the accreditation of medical institutes, clinical investigators and ethics committees engaged in clinical trials.

Publication: Pharmabiz
Edition: Online
Date: December 19, 2013
Headline: MM College of Pharmacy conducts week-long pharmacy practice training; opens DIC in Haryana

Synopsis: MM College of Pharmacy, Haryana has organised a one week training programme on pharmacy practice for pharmacy teachers which began on December 16, 2013 and will conclude on December 21, 2013. The event also saw the opening of the Drug Information Centre (DIC) which was established at the hospital attached to the MM Institute of Medical Sciences and Research, Haryana. Dr Pawan Krishan, professor and head, Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala discussed the issues related to clinical trials and role of pharmacy professionals in conduct of human studies.

General Industry

Publication: Mint
Edition: Online
Date: December 19, 2013
Headline: Angelina Jolie's mastectomy didn't help cancer awareness: study

Synopsis: Angelina Jolie's preventive double mastectomy, which the actress described in an editorial in the New York Times in May, didn't appear to improve understanding of breast cancer risk, a study found. The research, published on Thursday in Genetics in Medicine, surveyed more than 2,500 adults in the US three weeks after Jolie revealed that she had undergone the surgery because she carried a rare genetic mutation of the BRCA1 gene and had a family history of cancer. The survey found three out of four Americans were aware that Jolie had the operation.

Publication: Mint
Edition: National, Online
Date: December 19, 2013
Headline: Carlyle Group invests in Medanta

Synopsis: Global alternative asset manager The Carlyle Group on Thursday said its affiliate Anant Investments has made a strategic minority investment in Global Health Pvt. Ltd, which owns, manages and operates the super-specialty hospital 'Medanta—the Medicity' in Gurgaon, on the outskirts of Delhi.

Publication: The Times of India
Edition: National, Online
Date: December 19, 2013
Headline: Indian scientists invent insulin pills for diabetics

Synopsis: In a big breakthrough, Indian scientists have done what medical science has been trying to achieve since 1930 - an insulin pill for diabetics. Since insulin's crucial discovery nearly a century ago, countless diabetes patients have had to inject themselves with the life-saving medicine.

Publication: The Times of India
Edition: National, Online
Date: December 20, 2013
Headline: 'Specialty hospitals preferred even for minor ailments'

Synopsis: The Indian mentality of seeking admission in bigger hospitals for even minor ailments makes health insurers bleed, suggests a new survey on health insurance. It also showed India's health transition - from a hub for infectious diseases to non-infectious diseases - is reflected in its insurance patterns.

Publication: Pharmabiz
Edition: Online
Date: December 19, 2013
Headline: Stage set for 65th IPC, unfolding at Amity Noida from tomorrow

Synopsis: Stage is all set for the 65th edition of the three-day Indian Pharmaceutical Congress (IPC), beginning at Amity University, Noida, near here on Friday, bringing together as many as 4000 delegates from different areas of pharmacy and pharmaceutical industry, apart from the stakeholders and academics. For the first time, an online job portal has been introduced for the benefit of the large number of pharmacy students attending the event. Executives of several pharmaceutical companies are expected to interview the students for placement.

Publication: Exchange4Media
Edition: Online
Date: December 20, 2013
Headline: Competitive edge no longer resides in four walls of organisations: Niraj Dawar

Synopsis: A practical answer to this came from a pharmaceutical company producing a molecule for the ADHD medicines for children. To ensure that the value to the customer was maximised, this company, to check the effect of the drug decided to create video-games with lines of code telling the kids to calm down – and the effects were phenomenal. This goes to show that even if a particular task isn't exactly our forte, we can still accomplish it with external help, but simply ignoring it would help no one.

Access, Affordability, Innovation

Publication: The Economic Times
Edition: National
Date: December 19, 2013
Headline: Quadria Capital-led investor consortium picks up majority stake in Medica Synergie

Synopsis: Mid-sized Asian healthcare sector-focused private equity firm Quadria Capital, along with German and Swedish development finance institutions DEG and Swedfund, has picked up a majority stake in hospital chain Medica Synergie for an undisclosed amount. The investment by a consortium will be used to facilitate the growth of Medica's hospital network to over 1,300 beds and provide greater access to high-quality medical care in the region, according to a press statement released by the company.

Publication: The Economic Times
Edition: National
Date: December 19, 2013
Headline: In US healthcare experiment, patients pay more for 'bad' medicine

Synopsis: Obama's Affordable Care Act encourages doctors and hospitals to form Accountable Care Organizations (ACOs), which are paid more under the Medicare program for older Americans if they control costs while also providing quality care.

Publication: The Times of India

Edition: National
Date: December 19, 2013
Headline: TB online software spawns web of failure

Synopsis: Use of online web-based software 'Nikshay' , developed to facilitate TB registration and keep track of all missing cases, has not produced desired result on account of shortage of computers and human resource, health officials said. Nikshay is real-time software to register and identify TB patients. However, in reality 1,126 TB health workers on the field in Bhopal district without any computing device have no access to the software are still dependent on manual registers. Delayed online entry of data is manually handled in 50 district headquarters across MP.

Publication: Business Standard
Edition: National
Date: December 18, 2013
Headline: Strides Arcolab's subsidiary inks pact with German firm for ophthalmic drug

Synopsis: Strides Arcolab Ltd's subsidiary, Stelis Biopharma (formerly Agila Biotech), focused on biotherapeutic drug development and bio-manufacturing, and Germany-based Pieris AG, a next generation therapeutic protein R&D company, have entered into a long-term collaboration agreement for clinical development and commercialisation of multiple novel Anticalin-based protein therapeutics worldwide, primarily focusing on ophthalmology. Stephen Yoder, CEO, Pieris, stated, "Today's announcement is another example of how Pieris is finding innovative structures and committed partners to advance several Anticalins to the clinic in areas of high unmet need. Our strategic relationship with Stelis provides access to bio-manufacturing capabilities of the highest standard, yet in a very cost-effective manner."

Publication: Daily News and Analysis
Edition: National
Date: December 19, 2013
Headline: dna exclusive: Shivraj Singh Chouhan's mission 2018, Inclusive growth for all

Synopsis: According to the document, a copy of which is in possession of dna, the CM wants to rewrite history of the state by providing quality education to children and youth, access to proper healthcare for all and empowerment of women.

Publication: Pharmabiz
Edition: Online
Date: December 19, 2013
Headline: GE unveils innovative solutions for Neonatal Survival in India

Synopsis: GE Healthcare, the US$ 18 billion healthcare business of General Electric Company, has introduced a suite of new innovative solutions for the survival and growth of neonates in the primary care settings. Over the last decade there have been many advances in neonatal care, yet birth asphyxia and hypothermia remain leading causes of infant death and disabilities like blindness worldwide. There is a huge need to improve access to innovative solutions offering clinical performance, ease of use and affordability.

Publication: BizTech
Edition: Online
Date: December 18, 2013
Headline: Five Innovations That Will Change Our Lives Within Five Years: IBM

Synopsis: IBM is beginning to explore this opportunity, working with health care partners to develop systems that could deliver genomic insights and reduce the time it takes to find the right treatment for a patient from weeks and months to days and minutes. These systems are destined to get even smarter over time by learning about people, their genomic information and response to drugs – opening up the possibility to provide DNA-specific

personalised treatment options for conditions such as stroke and heart disease. Through the cloud, smarter healthcare could scale to reach more people in more locations, while also giving a global community of healthcare providers access to vital information.