News Updates: October 4, 2013

OPPI AGM

Publication: IndiaInfoline
Edition: Online
Headline: Veeva wins OPPI Sales Force Excellence Award 2013

Synopsis: Eli Lilly and company India (Lilly), the leading innovation based pharmaceutical player, was felicitated with the prestigious OPPI Sales Force Excellence award 2013 for its Project Veeva, aimed at delivering unparalleled customer experience by empowering the sales force. OPPI - Organization of Pharmaceutical Producers of India, instituted these awards to promote excellence in pharmaceutical selling in 2012. Lilly India was conferred with the honor at OPPI's AGM held in Mumbai. Much-coveted OPPI award was bagged by the project for achieving remarkable success and flawless execution of the project while carefully aligning the sales function with all other relevant functions and accordingly implementing Organization Change Management (OCM).

FDA

Publication: The Economic Times *(Reproduced from Reuters)*
Edition: Online
Headline: US FDA approves Pfizer drug for menopause symptoms

Synopsis: US health regulators have approved Pfizer Inc's menopause drug Duavee, which is designed to reduce hot flashes with fewer side effects than older hormone-replacement therapies. The Food and Drug Administration said on Thursday it approved the drug to treat women with moderate to severe menopause symptoms and to prevent post-menopausal osteoporosis, a bone disease which can increase the risk of fractures.

Publication: The Hindu Business Line
Edition: National
Headline: The Ranbaxy episode in perspective

Synopsis: Drug companies the world over have been pulled up, but Ranbaxy has raised awareness of the danger of non-compliance. It would be incorrect to say that the domestic industry woke up to the stringent regulatory requirements of the USFDA only after Ranbaxy's FDA experience. Those who ventured to the US market knew of the scope and mode of FDA inspections and audit. A further analysis of this data shows that in all, 66 companies received warning letters during the 42-month period. One company, Apotex, received two warning letters. Prominent among those receiving the warning letters are Boehringer Ingelheim, Hospira, Merck KGaA, Novartis, Novo Nordisk, Sanofi Aventis, SmithKline Beecham, Teva and Wyeth Lederle. Well-recognised companies including Apotex, Bausch & Lomb, Bayer, BMS, Cephalon, Genentech, Gilead, GSK, Greenstone, J&J, Mylan, Sandoz, Smith & Nephew, Teva, Watson and West Coast, have all been cited by the FDA.

IPR / Patents

Publication: Business Standard
Edition: All Editions
Headline: India's IPR regime - Moving beyond the myths of US pharma

Synopsis: It is time for the Indian government to address the growing trust deficit with foreign pharmaceutical manufacturers on the question of IPRs and improve the enforcement of patent protection.

The meeting between Prime Minister Manmohan Singh and US President Barack Obama on September 27, 2013, saw reaffirmations of what the leaders described as an "outstanding" and "indispensable" partnership, and of the US' support for the emergence of a "strong India". Implicit in their approach was the recognition that beyond the domestic political gridlock that currently preoccupies both leaders, India and the US also face daunting economic challenges. Understandably, the primacy of economic issues and invigorating economic growth was in the forefront of the Obama-Singh meeting agenda. It is well recognised by Indian policymakers that urgent steps are necessary to improve India's investment climate and revive economic growth. These must include, inter alia, strengthening the enforcement of intellectual property rights (IPRs).

Clinical Trials

Publication: The Economic Times
Edition: Online
Headline: Why Supreme Court is right to ask the government not to have clinical trials?

Synopsis: The Supreme Court is right to ask the government not to have clinical trials for new drugs till a mechanism is in place to monitor them. The real question is, why is the health ministry so tardy in putting in place a sound regulatory system to realise India's huge potential to carry out clinical trials on a large scale? Such trials can be hugely beneficial to millions of patients and also be a big boost for the pharma industry. There can be no compromise on the safety of human subjects participating in clinical research to discover the efficacy of a new drug. Amendments to the Drugs and Cosmetics Act, pending before Parliament, have penal provisions for failure to comply with norms to conduct clinical trials.

Publication: Pharmabiz
Edition: Online
Headline: SC order halting clinical trials may result in exodus of drug devpt innovators from India: Biocon chief

Synopsis: The Supreme Court (SC) ruling that puts a halt to clinical trials in India until the monitoring system is in place is a huge deterrent to drug innovation that can have an irretrievable impact on India's ability to partake in new drug development as it will lead to an exodus of innovators from India!, stated Kiran Mazumdar Shaw, CMD, Biocon. It is imperative that clinical trials are conducted on Indian patients to establish safety and efficacy of new drugs on our ethnic population to ensure access to new medicines.

Publication: Financial Chronicle
Edition: National
Headline: Singapore opens its doors for Indian biosimilar drugmakers

Synopsis: As economic slowdown progresses unhindered, demand for biosimilar drugs in developing economies is gaining momentum. Sensing this opportunity, Singapore is promoting itself as an attractive destination to biosimilar companies in India to set up manufacturing and R&D facilities and target the Asean and far east countries that seek cheap alternatives to expensive branded generics. Singapore is also ready to provide pre-clinical and clinical trials to Indian companies. This would be a boon to companies as regulatory issues in India make it very difficult for companies to go ahead with their clinical trials of non generic medicines.

FDI

Publication: Mint
Edition: All Editions
Headline: Govt clears 12 FDI proposals worth over Rs. 802 crore

Synopsis: The government on Wednesday said it has approved 12 foreign direct investment (FDI) proposals, including that of Ratnakar Bank, totalling over Rs.802 crore.Other major approved proposals include that of Hyderabad-based Mylan Laboratories to acquire an existing pharmaceutical manufacturing facility and of

OCS Group Singapore Pte Ltd for acquisition of equity shares of an Indian company engaged in business of detective and protective services. The ministry said, FDI proposals of Coimbatore based Ampo Valves India and Mumbai based Berggruen Real Estates have been rejected.

Drug Pricing

Publication: The Hindu
Edition: All Editions
Headline: **Drug prices: 'Govt. is being guided by market-driven forces'**

Synopsis: The Supreme Court has asked an NGO, which challenged the the new Drug Price Control Order, to place before it statistics on comparative analysis of drug prices under the new policy. The Supreme Court on Thursday raised a question on the new Drug Price Control Order of the Centre to fix the ceiling price of essential medicines on the basis of market-based pricing. A bench headed by Justice G.S. Singhvi said the Centre is being guided by market-driven forces and asked an NGO, which challenged the policy, to place before it statistics on comparative analysis of drug prices under the new policy and the existing market price.

General Industry News

Publication: Pharmabiz
Edition: Online
Headline: **'Pharma industry need to bring out advanced vaccines to meet threat of new epidemics'**

Synopsis: With the onset of new life threatening diseases and epidemics, there is a need for new vaccines and drugs to be rolled out besides making them accessible and affordable. In this context, experts advocate improvement of product quality and GMPs in the current global regulatory environment. Experts also emphasize the pharma analysts role in drug delivery to utilize available molecules in the existing drug delivery system. This according to them is possible through a proper system driven quality management system. This is more relevant in the current context as larger molecules, biosimilars, proteins etc can prove to be expensive in the Indian scenario because of socio- economic conditions.

Publication: Mint *(Reproduced from Bloomberg)*
Edition: Online
Headline: **BofA sees rupee drop creating China alternative for US firms**

Synopsis: Rupee's drop against dollar makes India more attractive amid rising wages in China, labour strife in Bangladesh. Bank of America Corp. (BofA), India's top-ranked takeover adviser, says the rupee's depreciation is generating interest from US companies for setting up factories in Asia's third-largest economy. "The Vodafone tax case did a lot of harm to India's reputation as an investor friendly destination," Sanofi chief executive officer Chris Viehbacher said on 30 September in Mumbai. The French drugmaker has disputed a claim by tax authorities to pay dues following the acquisition of India's Shantha Biotechnics Ltd.