News Updates: October 18, 2013

Clinical Trials

Publication: Business Standard
Edition: Online
Date: 18.10.2013
Headline: Regulatory hurdles hits US-based clinical research company's Phase I Unit

Synopsis: US-based Quintiles, which has a JV with Apollo Hospitals Enterprise Ltd, for clinical trials, has decided to close its Phase I unit in Hyderabad. The company said that the decision was due to challenging external business environment.

Website: NewScientist
Edition: Online
Date: 18.10.2013
Headline: Badly run trials behind Indian drug testing freeze

Synopsis: In recent years, India has emerged as the destination of choice for foreign companies looking to conduct clinical trials, attracted by low costs and access to a large pool of research participants. "Foreign companies are treating India as a heaven for clinical trials, but it is proving hell for India." So said an Indian Supreme Court judge on 30 September as he pressed the pause button on the country's clinical trials, ruling that all drug trials must be halted for two weeks. That period is now up, but there is no sign of the ban being lifted.

FDA

Publication: Business Standard
Edition: Online
Date: 18.10.2013
Headline: Pharma product approval time gets longer as regulators around the world go strict

Synopsis: Even as the Indian drug manufacturing industry is still looking for ways to wriggle out of the tightening regulatory noose of the US Food and Drug Administration (FDA), pharmaceutical companies have started facing a stringent environment in many other international markets too that contribute significantly to their revenues. With rising penetration of low-cost generic medicines, regulators across the globe have opted for stricter norms to ensure quality of medicines. For instance, regulators in major emerging pharmaceutical markets such as Brazil, Mexico, Russia and South Africa have changed various norms and guidelines for allowing sale of generic medicines in their respective markets. This is leading to considerable delays in approval processes as well as launch of medicines in these markets, directly impacting sales of major domestic players, say industry officials.

Publication: Pharmabiz
Edition: Online
Date: 18.10.2013
Headline: US FDA issues draft norms on patient advice info on labels of prescription drugs including biological

Synopsis: US Food and Drug Administration (FDA) has issued guidance on 'Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products' related to the content and format. The information is crucial for patients to use the drug safely effectively. In this regard, the regulatory

authority is awaiting the pharma industry to comment before the October 31.
According to the industry representatives from Biocon, Micro Labs and Bal Pharma, the guidance provides clear cut format on what should be indicated on the labels. “The purpose is to inform the patient about the contents and ensure his safety. In an age of an educated patient environment, it is only proper for the regulatory authority to come up with such rules.”

General Industry

Publication: IBN Live
Edition: Online
Date: 18.10.2013
Headline: Major pharmaceutical firm under scrutiny for producing spurious drugs

Synopsis: Fake drugs are one of India's worst kept secrets. Almost 45 per cent of drugs distributed in the country are manufactured in Himachal Pradesh and a major company based in the state, Vardhaman Pharmaceuticals, is under scrutiny for producing and distributing spurious drugs across the country. Filthy machines prepare spurious drugs at the medical factory which then go on to supply them to the central government, Tripura, Chhattisgarh and UP governments. After the Tripura government sounded an alert, Vardhaman Pharmaceuticals in Nahan, Himachal Pradesh, was put under surveillance by the state's drug control authorities.

Publication: Pharmabiz
Edition: Online
Date: 18.10.2013
Headline: CII to hold strategic IP management programme for pharma & biotech Nov 20 to 22 in Hyderabad

Synopsis: Confederation of Indian Industries (CII) is gearing up to organise a three-day ‘strategic IP management’ programme in pharma and biotechnology from November 20 to 22, 2013 in Hyderabad.
The main objective of the programme is to train and create awareness among the pharma and biotech industry particularly the middle level managements about the Intellectual Property Rights (IPR) and IP related issues in the pharma and biotechnology segments in India.