News Updates: November 8, 2013

Clinical Research / Trials

Publication: The Economic Times
Edition: National
Date: November 8, 2013
Headline: Drug regulator asks Sun Pharma to halt clinical research at Mumbai laboratory

Synopsis: The Drug Controller General of India has ordered Sun Pharmaceutical, the country's largest drug maker by market capitalisation, to suspend clinical research activities at its Mumbai-based bio-analytical laboratory, a move that could slow down the company's regulatory filings in India and possibly overseas as well. According to officials familiar with the matter, the drug regulator took the step after discovering that Sun didn't have the requisite approval from the central government for operating the laboratory.

Publication: The Hindu
Edition: National
Date: November 8, 2013
Headline: How can we make clinical trials safer?

Synopsis: It's usually the poor who live on the streets who sign up for these trials. Drug-makers should triple-check the ingredients in their goods and make sure they're suitable for usage. Human clinical trials should exclude the elderly and ill. Ill-literate people in want of money may try these researches. It should not happen. the sponsors must clearly inform them about the ill effects of the research. With all the necessary acceptance, Human clinical researches can be in practice. There must be mandatory insurance schemes for the people who involve themselves in such life-threatening tests and in case something unexpected happens, the families of people must be given high compensation amount, although money is not equal to the lost lives. In case of intense medical care needed, the same doctors must arrange for money and proper medical facility.

Publication: The Financial Express
Edition: National
Date: November 8, 2013
Headline: New drugs to hit market faster as govt tweaks trial policy

Synopsis: At a time when clinical trials (testing of new drugs on humans) have ground to a virtual halt in India due to a regulatory imbroglio and the resultant crackdown by the Supreme Court, the government is making an effort to make the relevant policy more pragmatic and conducive for the development of new medicines germane to Indian population. According to government sources, the health ministry has decided that introductory Phase I and exploratory Phase II clinical trials of new chemical entities (NCEs) being developed and to be marketed in India can be conducted abroad. This means the Indian drug regulator will approve data generated from trials conducted on foreign soil as far as these two phases are concerned. Based on such approvals, subsequent phases of trials — Phase III and IV — can be done in India. As per rules, all four phases of any new drug being developed to be marketed in India has to be conducted within the country.

Publication: Pharmabiz
Edition: Online
Date: November 8, 2013
Headline: Govt accepts Ranjit Roy panel report on approval of new drugs, clinical trials & banning of drugs

Synopsis: The Union health ministry has accepted the recommendations of the Prof. Ranjit Roy Chaudhury

expert committee which had recently submitted its report to the ministry. The committee was constituted by the ministry in February this year to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. According to senior officials in the ministry, the recommendations of the expert committee were discussed in a meeting with its members recently. During the meeting, clarifications on certain recommendations were obtained from the committee. After the meeting, the ministry in-principle accepted the recommendations of the committee.

FDI

Publication: The Financial Express
Edition: National
Date: November 8, 2013
Headline: Editorial: Pragmatic prescription

Synopsis: Given that the Planning Commission has now joined the finance ministry in opposing the Department of Industrial Policy and Promotion (DIPP) proposal to put curbs on pharma FDI, presumably the policy will die a natural death. While the DIPP had put up a big fight to prevent the $15 billion Mylan Inc from taking over Agila Specialities for $1.8 billion on grounds that facilities in 'critical verticals' like oncology, vaccines and injectables should not be sold to foreigners, this was turned down by both the prime minister as well as the finance minister on grounds the policy could not be changed with retrospective effect—right now, the policy allows 100% FDI without any restrictions. It is in response to this that the DIPP then came out with a proposal to, in the future, ensure that each FDI proposal to buy out local firms in select pharmaceutical categories is sent to the health ministry for a case-by-case approval.

FDA

Publication: Financial Chronicle
Edition: National
Date: November 8, 2013
Headline: Wockhardt shares surge 6% as UK regulator clears Kadaiya facility

Synopsis: The shares of Mumbai-based pharma major Wockhardt jumped 6.33 per cent on Thursday with analysts predicting UK Medicine and Healthcare Products Regulatory Agency's (MHRA) communication on the company's Kadaiya facility could be a major reason. Earlier the company has received an import alert on its export-oriented Waluj facility from MHRA and US FDA due to non-compliance regarding good manufacturing practices (GMPs). MHRA recently has issued a restricted GMP on Wockhardt's Chikalthana facility pot which the company is able to supply some essential drugs in the UK and Europe market.

Publication: Business Today
Edition: National
Date: November 8, 2013
Headline: Ranbaxy used fraudulent data for FDA nod, says whistleblower

Synopsis: Drug major Ranbaxy Laboratories used "fraudulent" data to get the US Food and Drug Administration's (USFDA) approval to sell its generic drugs, according to whistleblower Dinesh Thakur, who has also accused the drug-maker of faking test results. An ex-employee of the company, Thakur, who was tasked with investigations of alleged malpractices in the Ranbaxy, further said: "We started getting the files, and, lo and behold, we find that none of that exists in the first place. It means that we've gotten approvals from the FDA to sell drugs that were based on no data, or data that was fraudulent.

Publication: Pharmabiz
Edition: Online
Date: November 8, 2013
Headline: Gujarat FDCA recalls several sub standard drugs through e- governance system

Synopsis: Taking forward its programme of wiping out not of standard and spurious drugs Gujarat State Food and Drug Control Administration (FDCA) has recently stopped use, sale and distribution of medicines under the brand name Dexamac manufactured by Punjab based Inmac Lab, Oxytetracycline manufactured by Madhya Pradesh based Rainbow Laboratories, Trolin and Atofer manufactured by Himachal Pradesh based Laborate Pharmaceuticals and Metafenac manufactured by Gujarat based Dodel Laboratories.

Drug Pricing

Publication: The Economic Times
Edition: National
Date: November 8, 2013
Headline: Drug companies, distributors slugfest over margins

Synopsis: Drugmakers from GlaxoSmithKline to Lupin are grappling with Indian distributors, whose demand for maintaining commissions threatens to erode profits after India imposed price controls. Talks are under way after traders temporarily boycotted some treatments until their demands were met, Nilesh Gupta, managing director of Lupin, a maker of anti-tuberculosis medicines, said in an interview. Distributors want the terms of their commission to be restored after drugmakers slashed margins for traders following India's move to cap prices of 348 essential remedies.