



News Updates: October 22, 2013

Clinical Trials

Publication: The Times of India

Edition: National

Date: 22.10.2013

Headline: [SC orders video recording of clinical trials of new drugs](#)

Synopsis: The Supreme Court on Monday ordered the government to video record clinical trials of five new drugs, making it tougher for multinationals to shirk responsibility when testing of their patented medicine reacts adversely on patients.

Publication: Business Standard

Edition: National

Date: 22.10.2013

Headline: [SC has strict conditions for drug tests on humans](#)

Synopsis: Govt assures the bench that the procedure will be strictly followed. The Supreme Court on Monday relaxed its earlier stand on clinical trials of new drugs and chemical entities on humans but insisted on strict regulations being in place before approval of any tests.

Publication: The Hindu Business Line

Edition: National

Date: 21.10.2013

Headline: [Greater danger](#)

Synopsis: Clinical trials that conform to Good Clinical Practice regulations have several safeguards mandated even if Indian laws don't ("When clinical trials become dangerous", Business Line, October 16). These include informed consent and no enticement by monetary reward. Several new drugs are for diseases in patients who are high risk anyway.

Publication: The Hindu

Edition: National

Date: 22.10.2013

Headline: [Govt.'s tie-up with PATH for clinical trials kicks up row](#)

Synopsis: Health Ministry failed to act against PATH over HPV trials, allege Jan Swasthya Abhiyan, Brinda Karat. Health activists have expressed shock over the government's tie-up with One World Health (OWH), an affiliate of Program for Appropriate Technology in Health (PATH), for a training workshop on crisis management in clinical research for clinical trial professionals organised by the Department of Science and Technology.

Publication: The Hindu

Edition: National

Date: 22.10.2013

Headline: [Centre allowed to conduct five clinical trials](#)

Synopsis: Supreme Court Bench orders it to re-examine 157 GCT, including NCEs, by Apex and Technical

Committees. The Supreme Court on Monday allowed the Union government to conduct five clinical trials that were approved this year after ensuring proper mechanism and procedure to ensure the safety of patients along with audio-visual recording of participants maintaining the principle of confidentiality and preservation of documentation.

Publication: The Hindu

Edition: National

Date: 22.10.2013

Headline: [Ranbaxy gets thumbs-up for anti-malaria drug](#)

Synopsis: Ranbaxy Laboratories Limited on Monday said it had received the approval of the Central Drugs Standard Control Organisation (CDSCO) to manufacture and market Synriam™ for the treatment of uncomplicated malaria in adults caused by the Plasmodium vivax parasite.

Publication: The Indian Express

Edition: National

Date: 22.10.2013

Headline: [New anti-cancer drug in clinical trials](#)

Synopsis: Scientists have discovered a marker on leukemic stem cells and an antibody drug that binds to this marker is undergoing clinical trials in Australia and the US. Since the marker is specific for the cancer cells the treatment does not impact healthy cells - meaning that side effects may be limited, researchers said.

Publication: The Telegraph

Edition: National

Date: 21.10.2013

Headline: [Court extends trial ban on drugs](#)

Synopsis: The Supreme today extended its ban on clinical trials of 162 new drugs till December 16 and directed the government to ensure a "foolproof" mechanism for regulating such experiments that use human beings as guinea pigs. The court, which on September 30 had stayed the trials for two weeks, agreed to hear the matter again on December 16 after additional solicitor-general Sidharth Luthra sought further time to place on record a proper regulatory mechanism and rules for such clinical trials. Swastya Manch, an NGO, had first moved the court seeking a ban on the trials, saying Indians were being used as guinea pigs by several foreign pharmaceutical companies.

Publication: MoneyLife

Edition: Online

Date: 22.10.2013

Headline: [DrugDev and CFS Clinical Come Together to Drive Clinical Trial Standards for Investigators, CROs and Sponsors](#)

Synopsis: DrugDev, an interactive network and data sharing platform for over 80,000 clinical trial doctors in 93 countries, announced today its acquisition of CFS Clinical (CFS), the leading specialty provider focused on the business and financial management activities for clinical trials.

FDI

Publication: Moneycontrol

Edition: National

Date: 21.10.2013

Headline: [FDI in Pharma Sector: Past, Present & Future](#)

Synopsis: Drugs and pharmaceuticals form part of the basic necessities of the public at large. For this precise reason, India treats drugs and medicines as “Essential Commodities” and regulates their production and supply along with other essential commodities, such as sugar. In India, around the early 1970s, the bulk of the drugs production was done by Indian arms of multinational companies.

FDA

Publication: The New Indian Express

Edition: National

Date: 22.10.2013

Headline: [Now, Smruthi Organics under FDA lens for norms violation](#)

Synopsis: Yet another Indian pharma firm has come under the scanner of the US Food and Drug Administration (FDA) with the health regulator pulling up Smruthi Organics for violation of norms. It may be recalled that recently, several firms including Ranbaxy Laboratories, Aurobindo Pharma, Dr Reddy’s Laboratories and Wockhardt were under the FDA lens for alleged violation of Current Good Manufacturing Practices (CGMP) at their respective production units both in India and overseas.

DCGI

Publication: Pharmabiz

Edition: Online

Date: 22.10.2013

Headline: [Madras HC upholds govt's order banning manufacture, sale of dexypropoxyphene](#)

Synopsis: Madras High Court (HC) in its recent order has directed Wockhardt Ltd to restrain from manufacturing, marketing and selling the drug dexypropoxyphene under the brand name Proxyvon and Spasmo Proxyvon against the writ petitions filed by the company to get interim stay of operation of the notification on the ban. HC passed the order taking in view of the recommendations of Drugs Technical Advisory Board (DTAB).

Drug Regulatory

Publication: Mint

Edition: National

Date: 22.10.2013

Headline: [Ranbaxy gets regulatory nod for anti-malaria drug](#)

Synopsis: Ranbaxy gets CDSCO approval to manufacture and market Synriam for treatment of uncomplicated malaria in adults

Publication: Pharmabiz

Edition: Online

Date: 22.10.2013

Headline: [Pharmexcil seeks clarification on levy of service tax on transactions undertaken abroad by NTOs & subsidiary cos](#)

Synopsis: The Pharmaceuticals Export Promotion Council of India (Pharmexcil) has sought clarification from Service Tax department on the applicability of service tax on reverse charge basis on transactions undertaken outside India by non-trading offices (NTO) and subsidiary companies of Indian pharma companies.

Publication: Pharmabiz

Edition: Online

Date: 22.10.2013

Headline: [India yet to seriously take up loopholes in new EU regulation on customs enforcement](#)

Synopsis: India is yet to seriously take up with the European Union the alleged loopholes in the recent EU regulation on customs enforcement of intellectual property rights even as the public interest groups claimed that the new regulation was nothing better than the original one of 2003 that led to the seizure of Indian generic drugs and could pose serious hurdles again for Indian industry.

Drug Pricing

Publication: Moneycontrol

Edition: Online

Date: 22.10.2013

Headline: [US showing good growth; EMs steady: Unichem Labs](#)

Synopsis: The drug firm reported a 3.22 percent increase in net profit to Rs. 36.2 crore for the quarter ended September 30 as sales rose. Rakesh Parikh, CFO, Unichem Laboratories says the new drug pricing policy affected the company's domestic growth. The drug firm reported a 3.22 percent increase in net profit to Rs. 36.2 crore for the quarter ended September 30 as sales rose.

Patents / Compulsory Licensing / Intellectual Property Rights

Publication: The Economic Times

Edition: National

Date: 22.10.2013

Headline: ['India has failed to recognise IP rights; deterring investors'](#)

Synopsis: A US trade body has asked India to spur innovation and strengthen its intellectual property (IP) laws, saying failure to recognise IP rights was dissuading investors and keeping Indian economy in a logjam. Unfortunately, India has failed to recognise international property rights which is deterring investments in the country and keeping the economy in a logjam, he added. According to GIPC, the decisions against the protection of intellectual property rights made in India over the past year are negatively impacting businesses' ability to invest in medical and technological advancements. In April this year, Swiss pharma major NovartisBSE 0.04 % AG lost a seven-year long legal battle for getting its blood cancer drug Glivec patented in India and to restrain Indian companies from manufacturing generic drugs, with the Supreme Court rejecting the multinational company's plea. Novartis had approached the apex court in 2009 against the order of Chennai-based Intellectual Property Appellate Board (IPAB), which had rejected its claim for patent.

General Industry

Publication: The Economic Times

Edition: National

Date: 22.10.2013

Headline: [Dabur's Burmans Enter Healthcare , Partner with UK Firm](#)

Synopsis: The promoter of Dabur India is foraying into healthcare through a JV with UK-based Healthcare At Home with plans to invest around Rs. 200 crore.

Publication: Mint

Edition: National

Date: 22.10.2013

Headline: [The Era of Personalised Medicine](#)

Synopsis: People react differently to drugs based on how they metabolize, and the aim of pharmacogenetics is to assist in choosing the right medication for an individual. By 2014, the current cost

of Rs. 20-30 lakh is expected to dip to Rs. 2-3 lakh as there will be a 50% drop in the cost every year. It would make diagnosing a number of genetic disorders very affordable..

Publication: Business Standard – The Smart Investor

Edition: National

Date: 22.10.2013

Headline: [DIPP considering offering interest subsidy to manufacturing](#)

Synopsis: Worried over persisting slump in the manufacturing segment, the Commerce and Industry Ministry is working on a proposal on giving interest subsidy as part of its efforts to shore up growth in the sector. The Department of Industrial Policy and Promotion (DIPP) is discussing the proposal internally. In manufacturing, sectors which are doing very bad may get the benefit. Those areas will be decided during the meetings