News Updates: October 23, 2013

OPPI

Publication: Assocham
Edition: Online
Date: 23.10.2013
Headline: The Associated Chambers of Commerce and Industry of India

Synopsis: Mr. Tabrez Ahmad, Secretary General, The Organization of Pharmaceutical Producers of India (OPPI)

Fire in the Blood

Publication: The Times of India
Edition: National
Date: 23.10.2013
Headline: 'Fire in the Blood' to hit the screens on Oct 25

Synopsis: Fire in the Blood, a 90 minute film that exposes how pharma companies use patent laws to keep profits at the expense of peoples' lives, will be screened at Big Cinemas from Friday. While the multiplex has planned one show of this film every day, number of screenings will be increased based on response from the public.

Publication: The Asian Age
Edition: National
Date: 23.10.2013
Headline: The untold story of one of the biggest drug crimes

Synopsis: Indian-Irish filmmaker Dylan Mohan Gray's award-winning documentary Fire in the Blood that screened in theatres across India this month, turns the spotlight on one of the most contentious issues of our times — patents versus patients. In Fire in the Blood, a one-and-a-half-hour film, shot in 4 continents and starring ordinary and extraordinary men and women, Mr. Gray tells the story of Big Pharma's attempts to block low-cost AIDS drugs for Africa and other developing countries in the 1990s causing countless deaths and the improbable group of people who decided to fight back.

Clinical Trials

Publication: Business Standard
Edition: National
Date: 23.10.2013
Headline: Drug regulator 'goes slow' on clinical trials

Synopsis: Files related to clinical trial applications have stopped moving at the drug regulator's office, according to sources. This is in the wake of stringent directives from the Supreme Court asking the government and the regulatory agency to take measures to ensure safety of patients participating in clinical trials for testing of new medicines.

Publication: Hindustan Times
Edition: National
Date: 23.10.2013
Headline: Clinical trials and many errors

Synopsis: On Monday, the Supreme Court said no human trials of new drugs should be allowed without an audio-visual consent, giving its nod to only five of the 162 drug trials — related to new drugs (including new chemical entities) and new fixed-dose combinations — approved by the Centre. It ordered that clinical trials for

the 157 drugs must be cleared by the technical and apex committees set up by the Centre for this purpose. The clinical trials industry in India is estimated at $485 million in 2010 and is anticipated to cross $1 billion by 2016, says Frost & Sullivan's Strategic Analysis of the Clinical Research Organisation Market in India (2012). Large, easy-to-access, treatment-naive population and a high degree of available cost arbitrage of 30-50% over the US are driving the market, which is growing at 11-13% annually, it said.

Publication: The Indian Express
Edition: National
Date: 23.10.2013
Headline: Trials and errors

Synopsis: The problem with clinical trials is not weak rules, but the inability to enforce them. Clinical research in India has been in limbo since January 3, when the Supreme Court held back the Central Drug Standard Control Organisation (CDSCO) from granting permissions, after irregularities in the process were brought to its notice. While the health ministry had set up a committee to suggest improvements in the process, and the government had established a three-tier system with a new drugs advisory committee, a technical committee and an apex committee, it had also granted approvals to 162 trials in the interim.

Publication: The Indian Express
Edition: National
Date: 23.10.2013
Headline: Pharma cos may move clinical trials out

Synopsis: A day after the Supreme Court (SC) stopped permissions to 157 clinical trials, pharmaceutical companies said Tuesday they may be forced to move trials out of India. Dhananjay Bakhle, Executive Vice-President (Medical Research), Novel Drug Discovery & Development, Lupin Limited, said the regulatory environment and volatility therein, the uncertainty over the last two years was already discouraging and we started conducting clinical trials in other geographies such as Europe. If granted approvals are also being cancelled, there is no sanctity of governance. One has already noticed a sizeable decline in the number of trials and applications over the last 2 years.

Publication: The Times of India
Edition: National
Date: 23.10.2013
Headline: Bald truth: Treatment to boost new hair growth

Synopsis: A new experiment to regrow hair by cloning follicles and using discarded infant foreskins to graft them onto lab mice has shown some early success, researchers said Monday. The process generated new human hair in five of the seven animals on which it was tested, according to the study published in the Proceedings of the National Academy of Sciences.

Publication: Pharmabiz
Edition: Online
Date: 23.10.2013
Headline: Swasthya Adhikar Manch asks Health Min for position paper on how trials benefiting Indians

Synopsis: Swasthya Adhikar Manch, the NGO fighting against the irregularities in clinical trials, has asked the government to come out with a position paper on how the new chemical entities (NCEs) and new molecule entities (NMEs) are cleared for trials in the country. The NGO spokesman said they made the demand for the position paper in the affidavit filed in the Supreme Court on Monday, during the hearing of its petition filed in February 2012 alleging that the NCEs and NMEs were benefiting the multinationals at the cost of human lives in India.

FDA

Publication: The Economic Times
Edition: National
Date: 23.10.2013

Headline: Lupin gets USFDA nod for additional strengths of cholesterol drug

Synopsis: Drug major Lupin today said it has received US health regulator's approval to market additional strengths of Antara capsules, a cholesterol lowering drug, in the American market. The company has received final approval for its supplemental New Drug Application (sNDA) for Antara (Fenofibrate) capsules in 30mg and 90mg strengths from the United States Food and Drug Administration (USFDA), Lupin Ltd said in a statement.

Publication: Business Standard, Mumbai
Editions: National
Date: 23.10.2013
Headline: Indian Firms in the line of global fire

Synopsis: Wockhardt's manufacturing plant in Kadaiya, Daman, has come under the scrutiny of the UK health regulator. This is the company's third facility to face regulatory heat within a space of a few months. Last month, the US drug regulator had blacklisted Ranbaxy Laboratories' Mohali plant, stopping supplies to the US. According to a recent study by CphI, during January 2010-June 2013, about 66 companies, such as Ranbaxy, Novartis, Sanofi Aventis, Merck KGaA and Wyeth, had received warning letters from US FDA. In 2012, 12 per cent of these were received by Indian companies, which account for 40 per cent of drug master files (DMFs; for selling drug ingredients) and 37 per cent of abbreviated new drug applications (ANDAs; for selling formulations).

Publication: Pharmabiz
Edition: Online
Date: 23.10.2013
Headline: FDA officials book 4 quacks for misleading ads, selling drugs without license

Synopsis: With the Maharashtra Food and Drug Administration (FDA) massive crackdown on doctors selling medicines illegally over the past few months, four bogus medicos have recently been booked at Ratnagiri under the relevant sections of Drugs and Cosmetics Act, 1940, Drugs & Magic Remedies Act 1954 and Maharashtra Medical Practitioner Act, 1961 for exhibiting objectionable advertisement regarding treatment of impotence along with selling and stocking of drugs without a license.

Drug Pricing

Publication: The Economic Times
Edition: National
Date: 23.10.2013
Headline: Justice GS Singhvi: The quiet judge & unquiet times

Synopsis: A short list of Justice Singhvi's major judgments (See graphic) represent a long line of worries for India Inc and GoI. Justice Singhvi is also hearing the appeal against Delhi high court's decriminalisation of homosexuality, the PIL against 'improper' use of red lights and beacons on VIP vehicles, appeals against new official drug pricing formulas and the ban on 'gutka'.

General Industry

Publication: The Financial Express
Edition: National
Date: 23.10.2013
Page: 5
Headline: Pharma cos raise margins for retailers

Synopsis: In a bid to counter slowing sales, drug majors like Cipla, Mankind Pharma and Torrent decided to give in to traders' demands for higher margins. All three have increased trade margins for stockists and retailers to 10% and 20%, respectively, on the price-controlled basket of drugs, against the DPCO offered 8% and 16%, respectively, analysts said.
The move could impact their profit margins. According to Edelweiss Securities, the loss — on account of price control — can increase from anywhere between 10% and 24% if margins are paid on the retail price rather than on the purchase price

Publication: Pharmabiz
Edition: Online
Date: 23.10.2013
Headline: India to retain momentum in generics exports growth

Synopsis: Forecasting India will retain its explosive growth in generics exports (24 per cent for last four years) and commitment to lowering the cost of vital medicines through its development expertise, the Indian Brand Equity Foundation (IBEF) and Pharmexcil announced the country's plans for growth and its commitment to lowering the cost of medicines globally. Speaking at CPhI Worldwide event at Frankfurt, Germany, Dr P V Appaji, Director General, Pharmexcil said "during the last three years India's exports of pharmaceuticals have been growing at 17 per cent. We are expecting a CAGR of around 20 per cent in the next five years".

Publication: Mint
Edition: Online
Date: 23.10.2013
Headline: UK regulator withdraws quality certificate to Wockhardt's Daman plant

Synopsis: Drug maker Wockhardt Ltd said on Tuesday that the UK drug regulator, Medicines and Healthcare products Regulatory Agency (MHRA) has withdrawn a quality certification issued to the company's Kadaiya factory in Daman. This is the second manufacturing facility of Wockhardt to lose its certification by MHRA. The agency withdrew its certification of the company's factory in Chikalthana on 19 October. The Chikalthana facility received a negative report from the US Food and Drug Administration (FDA) in August. Wockhardt's Waluj injectable plant in Aurangabad also faces an import ban by the US.