News Updates: October 24, 2013

OPPI

Publication: Apothecurry
Editions: Online
Date: 24.10.2013
Headline: India & drug pricing : Now, list of essential meds questioned

Synopsis: In continuation of the challenges arising from the roll-out of India's new drug pricing policy, a question has now been raised on the current National List of Essential Medicines (NLEM) that specifies the universe of drugs under price control. Some may argue that the NLEM is not appropriately designed said Dilsher Singh Kalha, Secretary, Department of Pharmaceuticals (DoP) which administers the policy, addressing CEOs and senior executives at the annual general meeting of industry body OPPI three weeks ago.

Clinical Trials

Publication: India Health *(Reproduced from The Indian Express)*
Editions:
Date: 24.10.2013
Headline: Pharma companies consider leaving India over clinical trial ban

Synopsis: Angered by the Supreme Court's decision to stop 157 clinical trials, pharma companies are considering moving them out of India. It's believed that this uncertain scenario will in the long run harm India's image as a diverse location for clinical trials and also impact the availability of drugs in India. Dhananjay Bakhle, Executive Vice-President (Medical Research), Novel Drug Discovery & Development, Lupin Limited told The Indian Express, '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.'

FDA

Publication: Business Standard
Editions: National
Date: 24.10.2013
Headline: Zydus gets USFDA nod for phase-I clinical trial of diabetes drug

Synopsis: Ahmedabad-based Zydus Group today said that it has received the nod from the US drug regulator to start phase-I clinical trials for ZYDPLA1, a new molecule aimed at treating diabetes. A company statement here said close on the heels of launching Lipaglyn, the breakthrough therapy to treat diabetic dyslipidemia and India's first new chemical entity (NCE) to reach the market, the Zydus group announced the Phase I clinical trial approval from the US Food and Drug Administration (USFDA) for ZYDPLA1 - a next generation, long-acting DPP-4 inhibitor.

Publication: Pharmabiz
Editions: Online
Date: 24.10.2013
Headline: State FDA files FIR against Wockhardt for delayed recall of banned drug

Synopsis: The Maharashtra Food & Drug Administration (FDA) has filed an first information report (FIR) against Wockhardt Ltd at Loni Kalbhor Police Station, Pune for the delayed recall of banned drug dextyropropoxyphene. Fourteen FIRs have also been filed by the state FDA at several police stations of Kolhapur, Raigad, Bhiwandi, Alibaug, Mahad and Mumbai against its distributors across the state as over Rs. 45

lakhs worth of drug have been sold across the state despite the ban on May 23, 2013 prohibiting its manufacture and sale.

Publication: Pharmabiz
Editions: Online
Date: 24.10.2013
Headline: ICMR to conduct comparative study of Indian drug eluting stents with US FDA approved stent soon

Synopsis: Indian Council of Medical Research (ICMR) is planning to assess safety and efficacy of indigenous drug eluting latest generation stents and US FDA-approved drug eluting stent for a comparative study that may give a push to local manufacturers in the domestic stent market that is now dominated by foreign players now. ICMR will evaluate two latest generation Indian stents against one FDA-approved stent through sponsored trial with a view to give fillip to the development of indigenous technologies, products and gather data about safety and efficacy.

Publication: Reuters India
Editions: Online
Date: 24.10.2013
Headline: Repros says FDA seeks more studies for testosterone drug

Synopsis: Repros Therapeutics Inc said the U.S. health regulator sought additional studies of its testosterone replacement drug, Androxal, and recommended that a safety study of the drug be extended, delaying potential approval.

FDI

Publication: The Economic Times
Editions:
Date: 24.10.2013
Headline: Foreign Investment Promotion Board to consider Tata-SIA proposal on Thursday

Synopsis: The Foreign Investment Promotion Board (FIPB) will on Thursday take a call on allowing Singapore Airlines to tie up with Tatas for setting up a full-service airline, besides 29 other foreign direct investment applications. The FIPB, headed by Economic Affairs Secretary Arvind Mayaram, will also consider eight pharma sector proposals at the meeting. These include, Castleton Investment Ltd, Mauritius - GlaxoSmithKline Pte Ltd, Dastag UK, Perrigo API India Pvt Ltd and Intas Pharmaceuticals.

Patents

Publication: The Hindu Business Line
Editions: All editions
Date: 24.10.2013
Page: 4
Headline: US pharma firms lobby to protect patents in India

Synopsis: US pharma majors are putting pressure on the Government to stop issuing permits to domestic companies for making low-priced copies of patented life-saving drugs. Top officials from a number of US drug makers such as Pfizer, Mylan and Merck recently met the Department of Industrial Policy & Promotion (DIPP) Secretary to lobby against use of compulsory licences by India, a DIPP official told Business Line. A compulsory licence is a permit issued by a Government to local industry for producing copied versions of patented medicines without the consent of the patent holder.

Publication: The Economic Times
Editions: Delhi
Date: 24.10.2013

Headline: Emerging markets like Brazil, South Africa initiate reforms in patent laws in line with India's IP policy

Synopsis: Days before the Supreme Court ruled that Novartis' cancer drug Glivec is not a new invention good enough to be granted patent in April, a top executive of Pfizer had told a US Congress sub-committee, India's action reverberates far beyond its borders. That was perhaps the worst fear of Big Pharma, and it seems to be coming true with key emerging markets Brazil and South Africa initiating reforms in their patent laws in line with India's intellectual property policy. And global experts now expect other developing countries to follow suit.

DCGI

Publication: Pharmabiz
Editions: Online
Date: 24.10.2013
Headline: ISCR welcomes SC order asking DCGI to reconsider permission to conduct trials in 152 cases

Synopsis: The Indian Society for Clinical Research (ISCR) has lauded the Supreme Court order directing the clinical trial companies to re-examine the 152 human studies. The Court considered 162 cases for which approval has been given by the DCG(I) since the New Drug Advisory Committees were formed in 2011. The court expressed satisfaction with the process of approvals that were set in place for the trials approved since January 2013 and has asked that all trials approved before December 2012 should also have similar clearances to ensure the safety of patients in a clinical trial and minimize serious adverse events, according to ISCR.

General Industry

Publication: The Times of India
Editions: National
Date: 24.10.2013
Headline: Another Wockhardt plant under Medicines and Healthcare Products Regulatory Agency scanner

Synopsis: Mumbai-based Wockhardt Ltd said Britain's drug regulator has revoked the quality compliance certificate, or production licence, issued to its manufacturing plant in Gujarat. The company has received a communication from the Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom, whereby the agency has decided to withdraw the previously issued GMP (good manufacturing practice) certificate to the company's manufacturing facility at Nani Daman, Wockhardt said in statement to stock exchanges.

Publication: Zee News
Editions: Online
Date: 24.10.2013
Headline: Ghana committee to probe import of India-made drug

Synopsis: Ghana's health ministry has set up a ministerial committee to investigate the import from India of an anti-malarial medicine for children, Gsunate Plus, recently banned by the country's Food and Drugs Authority (FDA). A statement here by the ministry said a three-member ministerial committee has been set up to investigate the import and distribution of the medicine manufactured by Indian company Bliss GVS and imported by a local company, Tobinco. Last month, FDA said its investigations had revealed "no clinical trial study had been conducted on the product which is made up of the combination of Artesunate 25 mg and Amodiaquine 75 mg and manufactured by Bliss GVS Pharma Limited, located in Maharashtra, India.