News Updates: November 15, 2013

Fire In The Blood

Publication: The Economic Times, Business Standard *(Reproduced from PTI)*
Edition: National
Date: November 15, 2013
Headline: DIPP for stringent conditions in FDI in existing pharma companies

Synopsis: Faced with rush of multinationals to acquire Indian pharma firms, the commerce and industry ministry is proposing to tighten the FDI policy for the sector by incorporating conditions like mandatory investment in R&D and non-compete clause in the shareholders pact. The Department of Industrial Policy and Promotion (DIPP) has proposed these steps in its draft cabinet note for tightening foreign direct investment (FDI) in the existing domestic pharmaceutical companies.
As per the proposal, the foreign company would not be allowed to close down the existing R&D centre and would have to mandatorily invest upto 25 per cent of the FDI in the new unit or R & D facility, sources said. According to a media report, recently a 87-minute documentary - Fire in the Blood - has been making waves across the globe. It tells the story that how global pharma firms and governments have blocked movement of low-cost AIDS drugs to the African continent causing deaths of millions of people. "This documentary clearly reflects the true story of the western pharma companies," a source said. Currently, India permits 100 per cent FDI in pharmaceutical sector through automatic approval route in the new projects but the foreign investment in the existing pharmaceutical companies are allowed only through FIPB's approval.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Economic Times
Edition: National
Date: November 15, 2013
Headline: Natco Pharma rallies over 8% as US Court rejects stay request on Copaxone

Synopsis: Shares of Natco Pharma surged higher in trade today after the US Supreme Court rejected rival Teva Pharmaceutical's request for stay on Copaxone drug. Natco Pharma is in the process of developing generic version of Copaxone and can launch it in May 2014 subject to the USFDA approval. Copaxone accounts for about 20 percent of sales and 50 per cent of Teva's profit. The company generated nearly $4 billion in sales from the drug.

Clinical Research / Trials

Website: MoneyControl
Edition: Online
Date: 15.11.2013
Headline: Drug trials stuck in red tapes with no takers

Synopsis: Testing of new drugs for efficacy has slowed to a trickle in India and that has dashed hopes that the clinical trial industry would grow into a billion dollar industry by 2016. This is because the Supreme Court feel regulatory oversight in the sector is not adequate and has given the government time till December this year to come up with tighter set of guidelines. Until the new rules are finalised, there is a vacuum that players complain has led to delays.
But the government argues that it has to overhaul entire system to make such trials safe for patients. Also, the new, stricter rules will mean more trained manpower for oversight and that will take some time. The Supreme Court has also asked for a government scan of all global clinical trial applications to see whether the intent is to sell the final drug in the country. While this has made numerous activists happy, drug makers say this will only make for a longer approval process for genuine applicants.

Drug Pricing

Publication: The Economic Times
Edition: National
Date: November 15, 2013
Headline: Drug companies, traders to calculate loss due to new pricing policy

Synopsis: In the first concrete step toward resolving a tussle over margins of price-controlled drugs, pharmaceutical companies and distributors have decided to calculate "loss to trade channels" on account of the new pricing policy. However, the exercise of computing losses to drug distributors is being undertaken independently by both sides. This formula for resolution was arrived at a recent meeting attended by top department of pharmaceuticals officials and the National Pharmaceutical Pricing Authority, along with representatives from leading drugmakers and trade channels.

FDI

Publication: The Times of India
Edition: National
Date: November 15, 2013
Headline: Govt will cut expenditure to stick to deficit targets

Synopsis: Finance minister P Chidambaram has said that the government would make cuts in expenditure to ensure that it sticks to fiscal deficit targets. There have been large FDI proposals in the pharma sector and I think there will be at least one or two more cases of foreign direct investment in aviation. We are also seeing huge interest in telecom FDI, the finance minister said.

FDA / Drug Regulatory / DCGI

Publication: Business Standard
Edition: National
Date: November 15, 2013
Headline: Drug regulator set to conduct routine inspection of Chinese suppliers

Synopsis: The Indian drug regulator is set to conduct routine inspections at the manufacturing facilities of Chinese and other foreign companies supplying active pharmaceutical ingredients (APIs) to domestic pharmaceutical firms. The move follows a spate of international regulatory enforcements on Indian drug firms, which import more than 80 per cent of their API or raw material requirement for manufacturing finished formulations, mainly from China and Italy. The drug regulator, along with the commerce ministry, has already expedited talks with the Chinese government, regulator and industry to conduct these inspections on a routine basis. Drug Controller General of India (DCGI) G N Singh, back from a six-day trip to China last week

Publication: The Hindu
Edition: National
Date: November 15, 2013
Headline: Questions about India's drug industry

Synopsis: On May 13, 2013, Ranbaxy pleaded guilty to seven felonies relating to drug manufacturing fraud and agreed to cough up $500 million to settle the case brought by the U.S. Department of Justice (DoJ) after eight years of investigation. The vast evidence in the case, some of it supplied by Mr. Thakur and marshalled by the U.S. Food and Drug Administration (FDA), included inspection reports compiled after multiple FDA visits to Ranbaxy plants in India — in Paonta Sahib, Himachal Pradesh, and Dewas, Madhya Pradesh. According to the FDA's investigation, Ranbaxy acknowledged violations of cGMP regulations with regard to a U.S.-distributed drug, Sotret, even as far back as 2003. That was at a time when the billionaire brothers Malvinder and Shivinder Singh owned the company. The Singh brothers sold Ranbaxy to Japanese Daiichi-Sankyo in 2008 and walked away with a cool $4.6 billion.

Publication: Pharmabiz
Edition: Online
Date: November 15, 2013
Headline: EMA, US FDA issue responses to industry on 9 aspects of QbD for design space verification

Synopsis: European Medicine Agency (EMA) and the US FDA have issued their responses to the industry on nine aspects of Quality by Design (QbD) elements on design space verification. It would facilitate the implementation of QbD specifically on design space verification in both US and Europe. Early this year, two regulators, launched a pilot programme to allow joint evaluation of QbD elements. As a result of this pilot programme, the EMA and FDA reached agreements on a wide range of QbD elements.

Innovation in India

Publication: The Economic Times
Edition: National
Date: November 15, 2013
Headline: Cadila Pharma, Helperby sign licensing deal on antibiotic drug resistance

Synopsis: Ahmedabad-based Cadila Pharmaceuticals Ltd, a privately held drug company by Modi family and UK based antibiotics discovery company, Helperby Therapeutics have signed a joint agreement on antibiotic drug resistance Research & Development. UK's Prime Minister David Cameron hails the deal saying its another great example of UK-India collaboration. Described as the most important innovation in the discovery of new antibiotics since Alexander Fleming's original breakthrough more than 80 years ago, this announcement is a major breakthrough in the fight against resistance with the discovery of patented 'resistance breaker' compounds, a company statements said.