News Updates: November 27, 2013

OPPI

Website: afaqs
Edition: Online
Date: November 27, 2013
Headline: afaqs! to unveil Healthcare Brand Summit

Synopsis: The summit, which is the first of its kind, will be held on December 5 and 6 in Mumbai. OPPI has supported the event, while DDB Remedy is the knowledge partner.
While branding has become essential in the highly competitive market scenario for most products, the healthcare industry is slowly waking up to its merits now. With the Ministry of Health stepping up pressure to adopt prescription of generic drugs, it is especially become imperative for healthcare companies to indulge in brand building exercises. In an attempt to discuss the challenges and share experiences, healthcare and allied industries stakeholders are coming together for the first Healthcare Brand Summit. Organised by afaqs!, the summit will be held at Hilton Hotel, Mumbai, on December 5 and 6. The event is supported by OPPI and DDB Remedy is the knowledge partner.

Fire in the Blood

Publication: India Today
Edition: National
Date: November 27, 2013
Headline: Pill popper: Cipla's Yusuf Hamied changes fate of millions

Synopsis: A man puts a pill for AIDS in his mouth, and feeling a movement, puts his finger in, only to pull out a dead rat. It was an actual advertisement floated "in public interest" in the UK in the early 2000s to build resistance to India's sale of generic antiretroviral (ARV) drugs, then priced at $15,000, at $350 per person per year. The film Fire in The Blood, directed by Dylan Gray, previously an assistant editor on Deepa Mehta's Water, which won the Political Film Prize at Hamburg film festival this year, and which releases across India this week, tells the story of India's battle to slash prices of these life-saving medicines.

FDI

Publication: The Economic Times
Edition: National
Date: November 27, 2013
Headline: Commerce Ministry seeks 49% FII, FDI cap in existing drug companies

Synopsis: The Ministry of Commerce and Industry has proposed tighter overseas investment norms in existing drug companies by limiting all forms of foreign participation in them, including FII and FDI, at 49 per cent. Sources said the proposal is aimed at clarifying the level of overseas investment in the sensitive sector. It was earlier felt that foreign institutional investment (FII) could be over and above the FDI limit of 49 per cent. "The proposal now says that the cap would be 49 per cent (FDI + FII) in existing firms. The cabinet on Monday postponed the matter. It is expected to take it up soon," they added.

Publication: The Hindu Business Line
Edition: National
Date: November 26, 2013
Headline: MoC seeks 49% FII, FDI cap in existing pharma cos

Synopsis: The Ministry of Commerce and Industry (MoC) has proposed tighter overseas investment norms in existing drug companies by limiting all forms of foreign participation in them, including FII and FDI, at 49 per cent.
Sources said the proposal is aimed at clarifying the level of overseas investment in the sensitive sector. It was earlier felt that foreign institutional investment (FII) could be over and above the FDI limit of 49 per cent.
"The proposal now says that the cap would be 49 per cent (FDI + FII) in existing firms. The cabinet yesterday postponed the matter. It is expected to take it up soon," they added. Currently, India permits 100 per cent foreign direct investment (FDI) in new pharma companies through the automatic approval route. The same level is allowed for overseas investment in existing pharmaceutical companies, with approval from the Foreign Investment Promotion Board (FIPB).

Patents

Publication: The Economic Times
Edition: National
Date: November 27, 2013
Headline: Government mulls stricter norms for patents in pharma space

Synopsis: In a move that could usher in more transparency in the pharma patent landscape, the Indian Patent Office is considering a proposal that seeks to make it mandatory for drug firms to disclose the WHO-assigned generic names of drugs, whenever known, while applying for their patent. The proposal, if accepted, will make India the first country in the world to mandate such a condition. Experts say the move will make it easy for patent examiners, generic drug makers and public health groups to block 'frivolous' incremental patents from being granted. It will also make it difficult for innovator drug firms to get patents for incremental innovations, which do not show any enhancement in efficacy of an existing therapy.

FDA

Publication: DNA
Edition: National
Date: November 27, 2013
Headline: Maharashtra FDA Commissioner, Mahesh Zagade's Agenda paper at the Drugs Consultative Committee meeting held in New Delhi on November 12, 2013

Synopsis: Mahesh Zagade presented a document at the Drugs Consultative Committee that changed the focus of the meeting and turned it towards the average citizen.

Publication: DNA
Edition: National
Date: November 27, 2013
Headline: I will do all to safeguard public, says Mahesh Zagade

Synopsis: The Maharashtra FDA Commissioner insists every chemist shop must have a qualified pharmacist. In an interview with DNA, he said that there are some of the elementary provisions in various laws enacted in India for safeguarding the average consumer but few care to observe them. Unless the general public is more vigilant in implementing laws, the situation would not improve.

Publication: Forbes
Edition: National
Date: November 26, 2013
Opinion: Jeffrey Dorfman, Contributor
Headline: New Medicines Are Just Some Sensible Regulation Away

Synopsis: The current estimate of the cost to invent or discover a new drug, develop it, take it through trials, and get FDA approval is $1 billion. That cost does not include anything for the money spent on drugs that do not reach the end of approval process which can be considerable, especially if a drug gets near the end of the regulatory process before failing to clear a hurdle. What this means is that pharmaceutical companies are only interested in developing drugs that have the potential to earn very large profits, since such profits are necessary for the companies to recover the money they have spent on the development of both approved and failed drugs. It also means that next time you want to complain about the high price of prescription drugs remember that most of that price is to cover the cost of drug development and gaining regulatory approval.

General Industry

Publication: Pharmabiz
Edition: National
Date: November 27, 2013
Headline: BPPI shortlists 43 private cos for sourcing generic drugs for Jan Aushadhi

Synopsis: The Bureau of Pharma Public Sector Undertakings of India (BPPI), which is managing the Jan Aushadhi programme, has shortlisted 43 private companies in the preliminary round for supplying the generic drugs after it invited and opened the tenders. “The technical bids had been scrutinized and the visits to the factories of the selected companies were in progress to assess the parameters and finalise the list of suppliers. We hope to complete the process in another one week time,” according to a senior official of BPPI. He also disclosed that most of the companies shortlisted are mid-sized, though big pharma manufacturers also are in the list.

Publication: Mint
Edition: National
Date: November 26, 2013
Headline: Indian pharma market suffers from side effects

Synopsis: The Indian pharmaceutical market is facing a period of slow growth. One factor is the general economic slowdown. That may seem surprising but economic conditions do seem to affect spending on health. The more immediate problem for the industry is a cut in prices of drugs that have been included in a list of medicines covered under the new drug pricing policy. Lower prices have hit sales growth. This new policy has also resulted in trade channels protesting a lowering of their trade commissions by refusing to lift stocks from drug companies.

Publication: The Financial Express
Edition: National
Date: November 27, 2013
Headline: Several drugs banned abroad may face curbs in India as well

Synopsis: Over a dozen drugs, including anti-allergic Buclizine and anti-asthma Doxofylline, that have been removed from two or more foreign countries on grounds of efficacy and safety could soon find their way into the Indian government's “banned-drug” list, denting turnovers of pharma giants such as Glenmark, Ranbaxy, Lupin, Mankind and Cipla. Buclizine, prescribed in India as an appetite stimulant for children, is being marketed as Longifene by Mankind Pharma and this drug is also present in several combination formulations.

Publication: The Times of India(Similar reports in Mint, Business Standard, The Financial Express, The Hindu Business Line, Deccan Herald, Asian Age and The Pioneer)
Edition: National
Date: November 27, 2013
Headline: Biocon gets regulatory approval for breast cancer drug

Synopsis: Biopharmaceutical major Biocon has received marketing authorization from the DGCI (Drugs Controller General of India) for its biosimilar Trastuzumab to be used for the treatment of breast cancer. Biocon

is jointly developing the product along with US-based pharmaceutical company Mylan. Bangalore-headquartered Biocon claims that its drug Trastuzumab is the world's first biosimilar version of Herceptin, a registered brand of Swiss healthcare major Roche. The company said that it would market Trastuzumab in India under the brand name of CANMAb, which is expected to be available in the market in last quarter of the ongoing fiscal.