News Updates: 16 October, 2013

Fire in the Blood

Publication: Media Mughals
Edition: Online
Date: 16.10.2013
Headline: The Hollywood Reporter calls 'Fire In The Blood' a "very smart documentary from India" that "demands to be seen by as wide an audience as possible"

Synopsis: After making waves in numerous countries, Fire in the Blood screens today across India. Directed by Dylan Mohan Gray, the film has won critical acclaim worldwide. Rohit Khilnani from India Today wrote, "Dylan Mohan Gray's documentary 'Fire in the Blood' is "a shocking expose… A story that needed to be told to the world -- **** (4 stars)". According to noted film critic Rajeev Masand, the documentary is "A powerful, urgent film. Don't miss Fire in the Blood. It tells you how YOU can save lives". Sarit Ray from Hindustan Times says Fire in the Blood is "a sharp wake-up call... as riveting as it is engaging... the perfect vehicle for a powerful message that has been lost" and adds that "an Indian film might make it to the biggest awards stage... in a pill if not a lunchbox -- **** (4 stars)" Amongst India's leading opinion makers, Barkha Dutt tweeted "A Must Watch: Fire in the Blood @fitbmovie (releasing Friday) - hard-hitting & searing film on how Big Pharma blocked affordable HIV drugs".

Clinical Trials

Publication: The Hindu Business Line
Edition: All editions
Page: 8
Date: 16.10.2013
Headline: When clinical trials become dangerous

Synopsis: We do not have proper testing systems in place for drug molecules discovered abroad. At the heart of the clinical trial issue is the belief that all clinical trials are necessary and they somehow add to the GDP and pharma research capabilities of India. We will assume that to be true for the time being although the evidence in this regard is not clear. We need tighter regulations on clinical trials simply because most trial participants are vulnerable — their rights are not clear especially in the matter of compensation, even as the clauses already passed are being diluted. The laws regulating clinical trials seem to allow the trial sponsors to literally get away with the death of patients.

Publication: The Times of India
Edition: Online
Date: 16.10.2013
Headline: NHRC recommends stringent rules for clinical trials on humans

Synopsis: Following the incidents of pharmaceutical companies indulging in malpractices in conducting clinical trials on humans in 2011 in Hyderabad, the National Human Rights Commission (NHRC) has come out with guidelines on conducting clinical trial of drugs. The NHRC had constituted an expert committee in drug regulation and clinical trials which has come up with several recommendations. A standard Operating Procedure (SOP) should be followed in all clinical trials/clinical studies, based on the prevailing good clinical practices (GCP) guidelines issued by the Central Drugs Standard Control Organisation (CDSCO) and the Indian Council of Medical Research (ICMR). Several instances of deaths have been reported from other parts of the country during clinical trials. In fact, the parliament was informed that 436 people died during clinical trials in the country in 2012. In 2011, as many as 438 people had died and in the year 2010 there were as many as 668 deaths due to clinical trials.

Drug Pricing

Publication: Pharmabiz
Edition: Online
Date: 16.10.2013
Headline: Industry asks NPPA to amend order on 15-day time-limit for submitting representations on new prices

Synopsis: The pharmaceutical industry in the country has asked the National Pharmaceutical Pricing Authority (NPPA) to amend its order dated September 24, 2013 in which the national drug price regulator had decided that it will accept and respond to representations from manufacturers only if these representations are submitted within 15 days from the date of notification and such representations will be treated as time-barred and rejected. The industry wanted the NPPA to amend the order so that the 15 days time limit for representations should be applicable only from the date of availability of working sheets on NPPA website.

FDI

Publication: The Economic Times
Edition: Online
Date: 16.10.2013
Headline: FinMin not in favour of tightening FDI norms in pharma

Synopsis: The Finance Ministry is not in favour of tightening of norms for foreign investors in already existing Indian pharmaceutical companies. The Department of Industrial Policy and Promotion (DIPP) in its draft Cabinet has proposed to further tighten the rules for FDI in brownfield pharmaceutical sector. They have proposed several steps, including reducing FDI cap to 49 per cent in "critical verticals" of the sector from the current 100 per cent. Critical verticals include injectable in oncology (cancer related). DIPP is awaiting comments of the Planning Commission on this.

Publication: Business Standard
Edition: National
Date: 16.10.2013
Headline: FinMin not in favour of tightening FDI norms in pharma

Synopsis: Over 96% of the total FDI in the sector between April 2012 and April 2013 has come in brownfield pharma. The Finance Ministry is not in favour of tightening of norms for foreign investors in already existing Indian pharmaceutical companies, a senior official said. The Department of Industrial Policy and Promotion (DIPP) in its draft to Cabinet has proposed to further tighten the rules for FDI in brownfield pharmaceutical sector. They have proposed several steps, including reducing FDI cap to 49% in "critical verticals" of the sector from the current 100%. Critical verticals include injectable in oncology (cancer related).

Publication: The Hindu Business Line
Edition: Online
Date: 16.10.2013
Headline: Cracks in govt. over FDI in pharma

Synopsis: The current FDI regime that allows foreign investment in pharmaceuticals companies has become a bone of contention within the Government. Three Ministries — Finance, Commerce, and Health and Family Welfare — are strongly pitching for urgent reversal of the current policy which they feel threatens access to affordable medicines not only in India but also developing countries, including in Africa. The Prime Minister's Office is pitching for continuation of the policy. Incidentally, the Parliamentary Standing Committee of Commerce has recommended a blanket ban on FDI in existing pharma projects and urged that further takeover/acquisition of domestic pharma units be stopped.

FDA

Publication: India Today
Edition: Mumbai
Date: 16.10.2013

Headline: Maharashtra chemists oppose drug panel's decision, surrender licences

Synopsis: The Food and Drug Administration (FDA) and chemists are at loggerheads in Maharashtra. Around 3000 chemists have surrendered their licences. The FDA is trying to implement the mandatory rules of selling drugs under the supervision of registered pharmacist and that chemists should provide bill for every drug sold.

Publication: The Indian Express
Edition: Online
Date: 16.10.2013
Headline: Stop-sale-of-drug notice issued to 374 medical stores in Sept

Synopsis: Food and Drug Administration (FDA) authorities in a major drive carried out in September issued stop-sale-of-drugs notice to as many as 374 chemists in Pune division for failing to appoint pharmacists to dispense medicines. Of the 138 retail medical stores whose licences have been cancelled, 101 are based in Pune district.

Policy/ Regulatory Laws in Pharma

Publication: The Financial Express
Edition: National
Headline: Wockhardt shares tank on UK regulatory concerns put certification under uncertainty

Synopsis: Pharmaceutical major Wockhardt Ltd saw its shares sink on Monday after the UK health regulator withdrew the “good manufacturing practices” certificate issued to the company’s Chikalthana manufacturing facility in Aurangabad. The Medicines and Healthcare Products Regulatory Agency (UKMHRA) will now issue a “restricted GMP certificate” to the facility, which means the unit will be allowed to produce only certain critical drugs to avoid a shortfall in the UK. The Chikalthana facility — Wockhardt’s oldest manufacturing plant — is spread over about 6 acres and is approved to produce APIs and formulations. The facility produces generic version of the blockbuster cardiac drug Toprol-XL which contributed to 12% of the company’s sales in the fourth quarter, according to the transcript of a conference call with analysts.

Publication: Pharmabiz
Edition: Online
Headline: KSDCEOA urge state govt to strengthen DC dept to check unethical practices in drug trade

Synopsis: The Kerala State Drugs Control Enforcement Officers Association (KSDCEOA) has urged the state government to urgently restructure the department of drugs control to check the menace of unethical practices occurring in the fields of production and distribution of drugs in the state. The association stressed the necessity of strengthening the enforcement wing as it has felt that the regulatory mechanism in Kerala is currently not strong enough to control the drug distribution system and to implement the drugs and cosmetics act in its true spirit. The officers further urged the government to form a treatment protocol with priority on drug safety and wanted it to consider formation of a state drug policy.

General Industry

Publication: The Hindu Business Line
Edition: Online
Date: 16.10.2013
Headline: Govt allows import of drugs in small quantity for personal use

Synopsis: Government has allowed the import of drugs in small quanitities for personal use and patients requiring them will have to obtain a permit from the Drugs Controller General of India (DCGI).
As per the Drugs and Cosmetics Rules, 1945, the applicant is required to make an application in Form 12A along with the prescription of the Registered Medical Practitioner (RMP) and his registration number, indicating the quantity of drug required for the treatment of the patient. The rules also permit import of small quantities of drugs for exclusive personal use of the passenger as part of his bona-fide baggage.

Website: Pharmabiz
Edition: Online
Date: 16.10.2013
Headline: REVIVING JAN AUSHADI STORES

Synopsis: Opening a chain of retail medical stores for selling generic drugs under the Jan Aushadhi programme in 2008 was an excellent initiative on the part of Department of Pharmaceuticals. But the progress of this government initiative has been rather tardy even after five years. The Department was able to open only 157 generic stores so far in the country and out of that only 93 are currently functioning.