News Updates: 11 October, 2013

Fire in the Blood

Website: FirstPost
Edition: Online
Date: 11.10.2013
Headline: Fire in the Blood review: Good intentions, not-so-good execution

Synopsis: FirstPost has done a review of the movie 'Fire in The Blood'. The report talks about the movie plot which highlighted how Western companies had priced life-saving drugs that could treat AIDS exorbitantly high making it unaffordable for millions of people in South Africa. It also stated how Hamied started producing the same drugs at a fraction of the price and even distributed them for free. Along with crusaders like Dr Peter Mugyenyi and activists James Love and Zackie Achmat, he helped saved millions from suffering and hastened death.

The report further mentioned that though Fire in the Blood was made with good attention, it was shot unimaginatively and struggled to hold attention. The documentary feels dated, both in terms of technique as well as subject. Constantly looking back to the 1990s and early 2000s, it feels like a lecture that lacks insight. After all, that big American corporations are greedy liars is no revelation. It's also disconcerting to see Fire in the Blood ignore details like the stigma attached to AIDS in an effort to show India as the land of the brave as far as AIDS treatment is concerned. It's as though fear and misinformation about AIDS are a thing of the past in India.

Website: India Today
Edition: Online
Date: 11.10.2013
Headline: Movie Review: Fire in the Blood

Synopsis: India Today reviewed "Fire in the Blood" in its online edition today. It mentioned FITB as a documentary that will make one angry and upset. It's a shocking expose of western pharmaceutical companies that did not provide affordable AIDS drugs to patients and put company profits above the betterment of people. Millions were dying in Africa due to AIDS and medicines could be made available to them. But the western pharma lobby made that impossible, even when the medicines were affordable and many human lives could be saved.

FDA

Publication: Pharmabiz
Edition: Online
Date: 11.10.2013
Headline: US FDA seeks industry's comments on new draft norms on ANDA submissions

Synopsis: The US FDA has sought the pharma industry's comments on its draft guidelines on ANDA (abbreviated new drug application) submissions? Refuse-to-Receive Standards. Now in the case of India, ending June 2013, Indian pharma received 87 final approvals and 25 tentative ANDA approvals. Now the regulator has devised the draft guidance to assist sponsors in ANDA submissions. In addition, it has set up rules for prior approval supplements (PASs) to ANDAs for which the applicant is seeking approval of a new strength of the drug product. The draft describes on what should be included in an ANDA and highlights serious deficiencies that may cause FDA to refuse to receive an application to this effect.

Publication: The Times of India
Edition: Online
Date: 11.10.2013
Headline: FDA cancels licenses of 44 pharmacies

Synopsis: The Thane unit of Food and Drug Administration authority (FDA) has come down heavily on pharmacies operating without a pharmacist and cancelled licenses of 44 pharmacies across the city. The action was taken between April 1 and September 15.The FDA wants to ensure strict compliance of the rules, as sale of scheduled drugs without the supervision of a pharmacist is not allowed under the Drugs and Cosmetics Act, 1940.

Publication: Business Standard
Edition: Online
Date: 11.10.2013
Headline: Ranbaxy gets important breather

Synopsis: Ranbaxy's US factory, Ohm Laboratories, is learnt to have got a clean chit from the American regulator. This US facility was under surveillance of the Food and Drug Administration (FDA) since the end of 2012.This would enable Ranbaxy, owned by Daiichi Sankyo of Japan, to continue supplying from this unit; it could also allow it to shift some pending applications to Ohm from its Mohali unit in India, under an FDA import alert, to avoid delays in product launches.

Drug Pricing

Publication: The Economic Times
Edition: Online
Date: 11.10.2013
Headline: Government undecided over price cap on time-release drugs

Synopsis: Midway through the implementation of the new drug pricing policy, the government is facing a dilemma: should prices of time-release class of essential drugs be capped? While officials of the National Pharma Pricing Authority say the body has factored this set of drugs into its calculations, implying that they are covered under the new price control regime, the matter is being looked into again, even as the drug price regulator rolls out in phases new reduced prices for essential drugs. The drug price regulator fears that if prices in this category are not capped, drug makers may use it as a window to flee the price net by launching more drugs under his category.

General Industry

Website: The Times of India
Edition: Online
Date: 11.10.2013
Headline: 'Govt distributing poison under free drug garb

Synopsis: Addressing a gathering of the party's medical cell at Birla Auditorium, Former chief minister Vasundhara Raje alleged that the state government was distributing poison in the name of free medicines. She said there are complaints from across the state that drugs which are past their expiry dates are being distributed in the name of free medicines. If the scheme is doing so well, why has the state been pushed to 15th rank in terms of medical facilities?

Publication: The Hindu
Edition: Online
Date: 11.10.2013
Headline: Glenmark files lawsuit against six U.S. pharma firms

Synopsis: Glenmark Generics, on Thursday, said that its U.S. subsidiary had filed a lawsuit in the Court of Chancery of the State of Delaware, U.S., to enforce Glenmark's royalty-bearing licence agreement. A

statement from Glenmark said that it had an agreement with Triax Pharmaceuticals, Astellas Pharma Europe BV and Astellas Pharma International BV under which Glenmark is entitled to 180 days of exclusivity with respect to its Hydrocortisone Butyrate cream, as it is the first generic company to file an abbreviated new drug application (ANDA) for the product.

Publication: The Hindu
Edition: Online
Date: 11.10.2013
Headline: Insight: Big Pharma braces for retirement of favorite regulator

Synopsis: The retirement of Dr. Janet Woodcock as head of the Food and Drug Administration's pharmaceutical division is at least a year away, but already the industry she regulates is worrying about who will replace her. Over the past 20 years Woodcock, who is 65, has reshaped the drug approval process, relaxing the criteria needed for certain drugs to reach the market - especially those that represent scientific breakthroughs. Last year, the agency approved 39 new drugs, the most since 1996.

Publication: Business Standard
Edition: Online
Date: 11.10.2013
Headline: Elder Pharma CMD Saxena passes away

Synopsis: Jagdish Saxena, one among the veterans in Indian pharmaceutical industry and the chairman and MD of Elder Pharma has passed away on Thursday. He was 74 years old.