



News Updates: October 19-21, 2013

Fire in the Blood

Publication: The Times of India

Edition: National

Date: 20.10.2013

Page: 10

Headline: [India is committing selective genocide in healthcare](#)

Synopsis: The recent release of the documentary Fire in the Blood has revived the debate on whether patents block access to life-saving medicines. Dr Yusuf K Hamied, chairperson of Cipla and the 'star' of the film, made international headlines in 2001 when he offered to provide HIV medicines at \$350 per patient per year when the MNCs were selling the same for \$15,000. But now under the new patent law, generic versions of newer patented drugs cannot be manufactured here. Hamied tells Rema Nagarajan why there can't be a repeat of the 2001 triumph.

Publication: The Hindustan Times

Edition: National

Date: 20.10.2013

Page: 17

Headline: Lifting the veil off Big Pharma's Dirty Deeds (online link not available)

Synopsis: The Hindustan Times has published a report yesterday on the documentary Fire in the Blood. The report is based on an interview with the director Dylan Mohan Gray on what provoked him to make the documentary and highlights how Western pharmaceutical giants and governments blocked access to low-cost AIDS drugs in African countries in the mid-1990s, causing over 10 million deaths. The documentary is making an impact worldwide and it may also get a viewing in the White House.

Clinical Trials

Publication: The Indian Express

Edition: National

Date: 21.10.2013

Page: 4

Headline: [152 of 162 approvals given before new norms came](#)

Synopsis: As pharma majors await final word from the Supreme Court over clinical trials in India, the fate of 162 government-approved global clinical trials is set to hang in the balance further with the latest disclosure that 157 of them were cleared before the new regulatory regime. In a revelation that may jeopardise the prospect of a judicial nod for the clinical trials in the country, the Ministry of Health is going to inform the court that out of 162 approvals granted by the Drug Controller General of India (DCGI) till August 31 this year, 157 approvals were given in 2012. Only five approvals were given between January 1 and August 31, which involved scrutiny of cases by the Technical and the Apex Committee.

Publication: The Financial Express

Edition: Online

Date: 21.10.2013

Headline: [All eyes on SC as govt prepares its argument for clinical trials](#)

Synopsis: With policies governing approval and conduct of clinical trials embroiled in judicial and regulatory hurdles, India's potential for developing new drugs is under threat leading to far-reaching

consequences for patients.

On account of the limbo in approval of clinical trials, the industry estimates a loss of around \$150-200 million this year alone.

The Supreme Court will hear the matter on Monday, which will decide the future of 162 clinical trials — related to new drugs (including new chemical entities) and new fixed dose combinations — approved by the health ministry.

Publication: The Pioneer

Edition: Delhi

Date: 21.10.2013

Page: 5

Headline: [DCGI SEEKS CLARIFICATION ON INSPECTED CLINICAL TRIALS](#)

Synopsis: Days after the Supreme Court directed the Union Health Ministry to justify its approval for 162 global clinical trials in India, the Drug Controller General of India (DCGI) has sought clarifications in nearly half of the 577 clinical trials that it inspected. Sources said that the regulatory authorities inspected 577 clinical trial sites in last few years and notices were recently issued to the investigators/sponsors/ethics committees seeking clarifications in 235 cases.

Publication: Forbes

Edition: National

Date: 19.10.2013

Headline: [Clinical Trials and Safety: Not Mutually Exclusive](#)

Synopsis: India was once hailed as a fertile ground for clinical trials with a large drug-naïve population. Today, the international community, and its own apex court, is unconvinced. On September 30, the Supreme Court directed the Union health ministry to halt clinical trials in 162 cases where it had given approval until it provided assurances on safety regimes. It has given two weeks to the ministry before announcing a formal ban on clinical trials in the country. Nearly 40 trials involving the US National Institutes of Health are also on hold.

FDA

Publication: Pharmabiz

Editions: National

Date: 21.10.2013

Headline: [State FDA recommends CBI probe into defective medical device recall case](#)

Synopsis: Maharashtra Food and Drug Administration (FDA) has recommended the state Home department to handover the case related to Johnson & Johnson Ltd subsidiary De Puy Orthopaedics Inc.'s inappropriate recall of ASR Hip Replacement Implants in India to the Central Bureau of Investigation (CBI) for further investigation in the interest of over 4000 patients impacted by its use. Recommendation for CBI probe is the recent fallout of Mumbai High Court's (HC) order dated October 14, 2013 in response to the writ petition filed by De Puy Orthopaedics Inc for quashing the FIR filed by the state FDA related to not properly recalling the defective Hip Replacement Implant.

Publication: Mint

Editions: National

Date: 21.10.2013

Headline: [FDA ban's side effects: job losses](#)

Synopsis: Ranbaxy, Wockhardt fire 5% of shopfloor workforce following action by US regulator for violating norms

Publication: Daily News and Analysis

Editions: National

Date: 20.10.2013

Headline: [FDA makes prescriptions patient-friendly](#)

Synopsis: While doctors will need to write generic name of drugs, chemists will have to stamp

prescriptions to avoid reuse. Soon, doctors will have to follow a set of strict guidelines while writing a medical prescription. The guidelines include mentioning the generic and brand name of medicines, branch of medication (ayurveda, homeopathy, allopathy, etc) and the doctors' registration numbers. The Food and Drug Administration (FDA) is in the process of formulating the guidelines which will ensure safe prescriptions for patients. The officials recently met representatives from associations like modern medicine, ayurveda and unani to finalise the details.

FDI

Publication: Mint

Editions: National

Date: 21.10.2013

Headline: [FDA ban's side effects: job losses](#)

Synopsis: Ranbaxy, Wockhardt fire 5% of shopfloor workforce following action by US regulator for violating norms

Drug Regulatory

Publication: The Hindu Business Line

Editions: National

Date: 19.10.2013

Headline: [Another regulatory medicine needed](#)

Synopsis: The norms used to regulate drugs should not be mechanically extended to medical devices. In late 2005, Bombay High Court's then Chief Justice was surprised when informed that pace-makers and stents were not put through a regulatory approval process before they were sold in the country. The Court hearing was to do with the use of stents (wire-like devices inserted into blood vessels to remove blockages). The Court proceeded to instruct the Central and State drug regulators to formulate laws for medical devices. That, in a sense, kick-started the process of regulating medical devices — ranging from the humble surgical glove, cotton or syrup spoons to critical cancer imaging-equipment such as MRI machines, heart-valves, eye implants and drug-coated stents, to name just a few of the 2,000-odd devices estimated to be sold in the country.

Publication: The Hindu Business Line

Editions: National

Date: 20.10.2013

Headline: [Low-cost drugs scheme modified; will it work now?](#)

Synopsis: This November will mark five years since Jan Aushadhi, the Government's initiative to sell low-cost medicine, opened its first store in Amritsar. But, its record in the last five years has not been good. About 100 outlets operate at present, while another 50 have shut shop. Having learnt from its mistakes, the Government is giving the venture a fresh shot at success — as a more inclusive Jan Aushadhi (JA) format attempts to reach out to private drug-makers, civil society and consumers.

Publication: Pharmabiz

Editions: Online

Date: 18.10.2013

Headline: [IPC creates dedicated toll free number 1800-180-3024 to report adverse drug reactions](#)

Synopsis: In an effort to indicate its efforts to monitor the adverse drug reactions, the Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare created a Toll Free number facility under Pharmacovigilance Programme of India, to collect the adverse drug reactions with the use of medicines and to ensure patient safety.

Publication: FirstPost

Editions: Online

Date: 20.10.2013

Headline: [Allow import of new cancer drugs, says expert](#)

Synopsis: India could reap the benefits of new targeted cancer therapy provided its drug control authority allows the import of expensive cancer drugs, an expert said Sunday. Drugs like Imatinib and molecules like monoclonal antibodies – made by identical immune cells – are being increasingly deployed across the world to attack cancer cells specifically without causing harm to normal body cells.

Publication: Pharmabiz

Editions: Online

Date: 21.10.2013

Headline: [Health ministry allows import of prohibited drugs in small quantities exclusively for personal use](#)

Synopsis: In a decision that will benefit thousands of patients in the country who require some of the life-saving drugs which are not permitted to be imported or marketed in the country, the union health ministry has allowed to import such drugs in small quantities exclusively for the treatment of patients to save their lives. In the medical practice, sometimes drugs which are not permitted to be imported or marketed in the country are required exclusively for the treatment of patients to save their lives. So the ministry has decided to allow to import such drugs in small quantities to save the lives of patients, a senior officials in the ministry said.

Drug Pricing

Publication: The Hindu Business Line

Editions: National

Date: 19.10.2013

Headline: [Optimise R&D costs, don't raise drug prices](#)

Synopsis: In view of the increasing drug discovery expenses, it is essential to optimise research and development (R&D) costs rather than increasing the cost of medicines, according to T. Ramasami, Secretary, Department of Science and Technology. In his address at the third convocation of the National Institute of Pharmaceutical Education and Research, Hyderabad, held here on Saturday, he said fresh insights into disease biology may offer alternative models for cost-optimisation in drug discovery.

Publication: The Financial Express

Editions: National

Date: 19.10.2013

Headline: [Drug policy aimed at checking price: Govt](#)

Synopsis: It maintained drug pricing was a policy decision, which has been made by the experts. Defending its new Drug Price Control Order (DPCO) to fix the ceiling price of essential medicines on the basis of market-based pricing, the government has pointed out that the new regulatory framework sought to strike a balance between availability and affordability of medicines. It maintained drug pricing was a policy decision, which has been made by the experts, and so merits no interference by the court.

Publication: Telegraph India

Editions: National

Date: 20.10.2013

Headline: [New pharma players make their mark in US](#)

Synopsis: A new group of domestic pharmaceutical companies are making inroads into the US generics market, giving a tough competition to established players such as Sun Pharma, Lupin, Ranbaxy and Dr. Reddy's. Companies such as Intas Pharmaceuticals, Macleods Pharma, Hetero Labs and Indoco Remedies are focussing on research and looking to tap opportunities in the highly regulated and competitive American market.

Patents

Publication: The Times of India

Editions: National

Date: 21.10.2013

Headline: [Must strive to remain one of the biggest pharma exporters](#)

Synopsis: Experts on Friday stressed on the importance of pharmaceutical analysis in modern day research and also the need for moving ahead in the field at the global arena. They were speaking at a National Conference on Pharmaceutical Analysis (NCPA) organised by the chemical technology department of the Dr Babasaheb Ambedkar Marathwada University (BAMU). The head of the department of chemical technology of Bamu, Pravin Wakte, said, With each passing day, we in India need a new set of analytical skills. Our country, being one of the biggest exporters of pharmaceutical drugs in the world, has many challenges to deal with. Each country has a different set of stringent laws and requisite standards, when it comes to the import of drugs and we have to reach up to the highest quality standards so as to remain and keep growing as one of the biggest exporters in the world.

Publication: Business Standard

Editions: National

Date: 19.10.2013

Headline: [Cheaper generics making regulators more stringent](#)

Synopsis: Regulators across the globe have opted for stricter norms to ensure quality of medicines. Even as Indian drug makers are looking for ways to wriggle out of the tightening regulatory noose of the US Food and Drug Administration (FDA), pharmaceutical companies have started facing a stringent environment in many other international markets.

General Industry

Publication: The Economic Times

Edition: Online

Date: 18.10.2013

Headline: [Barcode procedures for pharma companies simplified](#)

Synopsis: In a move to simplify barcode procedures for pharmaceutical companies, the government has decided to treat mono cartons containing medicines also as primary level packaging. "Mono cartons containing strips/vials/bottles shall be treated as Primary level packaging," Directorate General of Foreign Trade (DGFT) has said in a public notice.