

Media Coverage: 2-3 October, 2013

OPPI AGM

Publication: MoneyControl - CNBC TV18

Edition: National **Date:** October 1, 2013

Headline: Govt rebooting Jan Aushadhi Stores

Synopsis: To ensure interest from private firms, the government has expanded the list of drugs sold at these stores from 100 to over 360, including all of the essential drugs. And that's just step 1. To ensure interest from private firms, the government has expanded the list of drugs sold at these stores from 100 to over 360, including all of the essential drugs. And that's just step 1. Dilsher Singh Kalha, Secy, Dept of Pharma said, "The list of drugs is even beyond the list of essential medicines and we have already floated the tender. It will take 3 months to close the tender process."

Drug Pricing

Publication: The Economic Times

Edition: National Date: October 2, 2013

Headline: Medicines to get lot cheaper under new drug price policy

Synopsis: Getting better is getting cheaper. The new drug price policy, the first after 18 years and expected to fully come into effect over the next six months, will reduce average middle class household spend on medicines by over 20%. For some crucial medicines, savings could be as much as 50% or more. A 2007 McKinsey report had predicted that healthcare spend will account for 13% of average household budget by 2025, the third-largest expenditure category after food and beverages and transportation. More so because the biggest beneficiary of the policy will be the growing middle class, which spends a large part of its regular healthcare budget on medicines treating lifestyle-related diseases like diabetes and hypertension. Price cuts will be the steepest in this class of drugs. The domestic drug market is worth Rs 70,000 crore, and 20% of it is accounted for by "essential drugs". Essential drugs in government terminology include life-saving and other most commonly used drugs, and medicines for most lifestyle-related diseases.

Patents

Publication: The Financial Express

Edition: National **Date:** October 2, 2013

Headline: Pharma Inc prepares to scale patent cliff, eyes \$50-billion market

Synopsis: With the \$50-billion drug market potentially up for grabs over the next five years due to a flurry of patent expirations, leading Indian drug companies are reinventing the high-risk-high-reward para-IV route. A generic company's preemptive para-IV submission allows it to challenge a patent and launch a generic version of the drug at the risk of being sued by the innovator or sell a drug that has just gone off-patent with the patent holder being the only competition.

Clinical Trials

Publication: The Economic Times

Edition: National Date: October 2, 2013

Headline: Supreme Court stays DCGI nod to 162 clinical trial applications

Synopsis: The Supreme Court has stayed approvals granted to 162 applications for clinical trials in the country and asked the sector regulator to provide evidence that norms for drug-related research are being followed. The order, issued on Monday, was in response to a petition filed by a health activist group. It is the latest in a series of measures the top court has taken following allegations of violation of clinical trial norms in the country. The DCGI has been given two weeks' time to reply.

Publication: The Economic Times

Edition: National Date: October 3, 2013

Headline: Delay in approvals unacceptable: Gujarat CROs

Synopsis: Gujarat's contract research organisations (CROs) have reacted strongly to the Supreme Court order staying approvals for 162 clinical trials in the country and said any delay in approvals will be a violation of "Right to Life guaranteed by the Constitution". The apex court has asked the sector regulator to show within two weeks that all drug-related research guidelines were being followed.

Publication: Pharmabiz Edition: National Date: October 3, 2013

Headline: Supreme Court seeks report on HPV vaccine trials by PATH in Andhra, Gujarat

Synopsis: The Supreme Court has sought a report from the Centre on the reported irregularities during the conduct of studies using Human Papilloma Virus (HPV) vaccine by international organisation PATH in Andhra Pradesh and Gujarat. The notice to the Centre was issued by the Apex court during a hearing on the ongoing case about the violations of norms during the clinical trials on a petition filed by public interest organisation Swasthya Adhikar Manch.

Publication: The Hindu Business Line

Edition: National Date: October 2, 2013

Headline: Delays in clinical trials will deter innovation: Biocon's Shaw

Synopsis: The recent ruling by the Supreme Court halting clinical trials on new drugs until the Health Ministry is able to monitor the process will deter innovation, says Kiran Mazumdar Shaw, Chairman and Managing Director, Biocon. Biocon has two novel molecules under development in India. One is a new oral insulin drug, which the company believes will transform treatment for diabetes. The development trials on this molecule have been delayed as the company awaits regulatory clearance to conduct additional tests. The earlier trials faced a setback, says the company. Trial results were impacted by selection of patients and drug administration not being 'optimal'.

Publication: Business Today – India Today

Edition: National Date: October 2, 2013

Headline: Supreme Court for proper mechanism on clinical trials

Synopsis: No clinical trials of untested drugs as part of global clinical trials, including those of new chemical entities (new molecules), should be allowed in India without a proper monitoring mechanism in place, the Supreme Court said on Monday, according a representative of the NGO Swasthya Adhikar Manch. The apex court will review the matter after all the data is in place. It will hold the next hearing on this on October 21.

FDI

Publication: Business Standard

Edition: National Date: October 2, 2013

Headline: Restricting FDI in pharma may prove counter-productive

Synopsis: The department of industrial policy and promotion (DIPP) has circulated a Cabinet note proposing restrictions on foreign direct investment (FDI) in the pharmaceutical industry so that Indian firms manufacturing "critical" drugs cannot be taken over easily by foreign entities. This is because India has historically played a key role in developing life-saving drugs at affordable prices, making the industry a major exporter and enabling it to play an important role in delivering India's own health security.

Publication: The Times of India (Reproduced from Agencies)

Edition: Online
Date: October 2, 2013

Headline: US impasse not to affect Indian economy: Govt

Synopsis: The government sees no major impact on India due to the US shutdown . "We hope the impasse will be resolved so that there is no spillover to the global economy. As of today, I don't see any major impact on the Indian economy on that account ," said economic affairs secretary Arvind Mayaram. The US government on Tuesday began the shutdown as Republicans and Democrats failed to strike a deal on spending and budget mainly due to their differences over 'Obamacare' , the flagship healthcare programme of President Barack Obama.

General Industry

Publication: The Economic Times

Edition: National Date: October 2, 2013

Headline: Ranbaxy may shift key drug filings from Mohali to US

Synopsis: Ranbaxy Laboratories may consider plans to shift some of its drug filings from its Mohali plant to its US-based Ohm Labs facility, after the former was barred from exporting drugs to the US market last month, analysts feel. A company spokesperson refused to comment on whether it is planning to shift its key drug filings from Mohali to US-based Ohm Labs.

Publication: Business Standard

Edition: National Date: October 2, 2013

Headline: India keen to tie up with Dubai's booming biotech industry

Synopsis: India has initiated a strategy to encourage and educate Indian investors to tap the potential of the UAE's thriving biotech sector. A free zone dedicated to facilitating and fostering the growth of the life sciences industry in Dubai is part of the UAE government's ambition to increase the amount of medicines manufactured locally.

Publication: The Hindu Business Line (Reproduced from PTI)

Edition: National Date: October 2, 2013

Headline: <u>Unfair practices in pharma sector under CCI lens</u>

Synopsis: Emphasizing that pricing aspects of pharmaceuticals are critical for the general public, CCI Chairman, Ashok Chawla, has said that some cases of probe into alleged unfair practices in this space are in the "pipeline". The Competition Commission of India has already slapped penalties on some entities, including chemists and druggists associations, for indulging in unfair trade practices. According to him, the Commission has already looked into many cases on the pharmaceutical retail side, while penalties have also been imposed on entities for adopting restrictive practices and not allowing others to enter the trade. That is an important area from our

point of view because pharmaceutical retail and prices at the consumer end impact a very large number of the population.