**News Updates: November 1, 2013**

## Clinical Research / Trials

**Publication: Pharmabiz**
**Edition: Online**
**Date: November 1, 2013**
**Headline: HAI raises demand for making entire data of clinical trials publicly available**

**Synopsis:** Even as India is still struggling to bring in basic standards of transparency in the clinical trials sector, international public interest groups are mounting pressure on the regulatory authorities elsewhere to make the entire clinical trial data publicly accessible. The Health Action International (HAI), a global network working on access to essential medicines, has urged the European Union authorities to take steps in this regard. The demand is likely to have a resonance in India also, where health activists are aggressively pushing for greater transparency in the clinical trials sector.

## FDA

**Publication: Reuters India**
**Edition: Online**
**Date: November 1, 2013**
**Headline: U.S. FDA outlines plan to combat drug shortages**

**Synopsis:** The U.S. Food and Drug Administration released a strategic plan for preventing drug shortages on Thursday and proposed a rule to require drug and biotechnology companies to promptly notify the agency of potential disruptions to the supply of medically important drugs.

## Drug Regulatory / Policy

**Publication: NDTV Profit**
**Edition: Online, Electronic**
**Date: November 1, 2013**
**Headline: New drug policy, regulations slowing down pharma growth: report**

**Synopsis:** Hit by the new drug pricing policy and regulatory interventions, growth rate of the Rs. 72,069-crore Indian pharmaceutical market has slowed down to9.8 per cent in 2013 as compared to 16.6 per cent in 2012, says a report. The pharma industry is also witnessing challenges like delays in clinical trial approvals, uncertainties over the FDI policy, a uniform code for sales and marketing practices and compulsory licensing, according to the report by CII-PwC.

**Publication: Business Standard**
**Edition: National**
**Date: November 1, 2013**
**Headline: Pharmaceuticals Purchase Policy (PPP) renewed for 5 years**

**Synopsis**: The Union Cabinet today approved the Pharmaceuticals Purchase Policy (PPP), for a period of five years. The renewal of the PPP aims at ensuring optimum utilization of the installed capacity of the pharma CPSEs. It

would not only provide necessary fillip in reviving these CPSEs, which are ailing but also ensure availability of quality medicines at low prices to the masses besides ensuring drug security of the nation. Pharmaceuticals Purchase Policy in respect of 103 medicines would be valid for a period of five years from the date of issue of orders by Department of Pharmaceuticals.

## Patents / Compulsory Licensing / Intellectual Property Rights

**Publication: FirstPost Business**
**Edition: Online**
**Date: November 1, 2013**
**Headline: BDR's compulsory licence bid for cancer drug rejected: What it means**

**Synopsis:** The Indian Patent Office has rejected Mumbai-based BDR Pharmaceuticals' application for a compulsory licence to make a generic version of US drug maker Bristol-Myers Squibb's anti-cancer drug Dasatinib, said media reports today. The development comes as a disappointment to millions of patients suffering from chronic myeloid leukemia as the drug won't be accessible to many because of its high price. In India, a month's dose of the drug costs about Rs 1 lakh. BDR had applied for the licence in March and said it would sell the drug for Rs 8,100 a month.

## Drug Pricing

**Publication: The New Indian Express**
**Edition: National**
**Date: November 1, 2013**
**Headline: 'Drug pricing policy, regulations slowing down pharma growth'**

**Synopsis:** The new drug pricing policy and tightened regulatory environment have collectively dragged down the growth of Indian pharmaecutical market to single digit at 9.8 per cent in financial year 2012-13 as against a healthy 16.6 per cent a year ago. The joint report by CII-PwC titled 'India Pharma Inc: Changing Landscape of Indian Pharma Industry', also said challenges such as delays in clinical trial approvals, uncertainities over the FDI policy, a uniform code for sales and marketing practices and compulsory licensing are plaguing the industry's growth.

## FDI

**Publication: Business Standard**
**Edition: National**
**Date: November 1, 2013**
**Journalist: Reghu Balakrishnan**
**Headline: Slowdown brings Indian pharma growth down to 9.8%: PwC report**

**Synopsis:** The slowdown in Indian economy has its negative impact over growth of Indian pharmaceuticals industry.According to the recent report from CII- PwC, overall pharma has experienced a slowdown with its growth going down to 9.8% from 16.6% in 2012. The industry is witnessing additional challenges like delays in clinical trial approvals, uncertainties over the FDI policy, a uniform code for sales and marketing practices and compulsory licensing. India is perceived as an attractive destination for clinical trials but has been marred with genuine concerns, it said.

## General Industry

**Publication: The Times of India**
**Edition: Mumbai, National**
**Date: November 1, 2013**
**Headline: Pharma market valued at Rs 72,069 crore: CII-PwC report**

**Synopsis:** The Indian pharmaceutical market (IPM) is currently valued at Rs 72,069 crore as against Rs 65,654 crore in 2012. Though the market value has seen an increase, the sector overall has experienced a slowdown with its growth going down to 9.8% from 16.6% in 2012. This slowdown can be attributed to the new drug pricing policy and the regulatory interventions over the last year, according to the CII-PwC report, 'India Pharma Inc; Changing Landscape of Indian Pharma Industry.' The report released at the CII Pharma Summit in Mumbai on Thursday.

**Publication: The Hindu Business Line**
**Edition: Chennai, National**
**Date: November 1, 2013**
**Headline: Driving Govt, programme for superior public healthcare** *(No link available)*

**Synopsis:** Prioritising and delivering essential medicines to vulnerable populations who are in urgent need is a major global challenge. Equally challenging is the need for limiting consumption of non-essential and expensive medicines by those who do not need them. Improving overall governance and accountability of medicine supply system is absolutely essential to make medicines available to one and all.

## Research & Innovation

**Publication: Pharmabiz**
**Edition: Online**
**Date: November 1, 2013**
**Headline: New medical device regulation to boost innovation: Experts**

**Synopsis:** Enactment of the new medical device regulation, the Drugs and Cosmetics Amendment Bill 2013, which is to be introduced in Parliament soon, would translate the medical devices into an affordable and user-friendly products. This according to experts will be the outcome of right differentiation between drug and device which would further boost innovation. This would also help in categorization of medical devices into different types - capital equipment, implants, consumables, in-vitro diagnostics which will further facilitate the process of regulating them.