



News Updates: May 21, 2014

OPPI

Publication: The Hindu Business Line

Edition: National

Date: May 21, 2014

Opinion piece: Ranjana Smetacek, Director-General of the Organisation of Pharmaceutical Producers of India

Headline: [For another line of treatment](#) (scan attached as well)

Synopsis: One of the challenges for the government will be to make quality healthcare accessible to all. In the past, this has been seen primarily as a matter of cost — making the services of a doctor or hospital facilities or medicine cheaper. However, a study last year by the IMS Institute for Healthcare Informatics — Understanding Healthcare Access in India: What is the Current State? — called for a holistic approach. It identifies four dimensions of healthcare access: proximity and the location of healthcare facilities; availability and capacity of required resources; quality of services needed for patient treatment; and affordability of treatment relative to a patient's income.

John J Castellani's blog on Elections- May 21, 2014

Publication: The Economic Times

Edition: National

Date: May 21, 2014

Headline: [Incoming Narendra Modi government represents opportunity to US business: PhRMA](#)

Synopsis: The incoming Modi-led government represents an 'excellent opportunity' for American industries to strengthen and rekindle their relationships with India, a leading US industry body has said. "Research-based bio-pharmaceutical companies see much potential for Mr Modi's success, because he understands the crucial role innovation plays in economic development," Pharmaceutical Research and Manufacturers of America (PhRMA) President and Chief Executive Officer John J Castellani said in a blog.

Similar reports in-

Business Standard- [Incoming Modi govt has 'excellent opportunity' for American industries: US](#)

The Hindu Business Line- [US business hopes on new Govt](#) (link unavailable, scan attached)

The Hans India- [American pharma leaders bullish on India](#) (link unavailable, scan attached)

Deccan Chronicle [Incoming Modi govt represents opportunity to US Biz: PhRMA](#)

NDTV- [US Pharma Companies Eye Opportunities Under Modi Government](#)

Free Press Journal- [Incoming Modi govt represents opportunity to US Biz: PhRMA](#)

Patents/ Intellectual Property/ Compulsory Licensing

Website: Pharmabiz

Edition: Online

Date: May 21, 2014

Headline: [Countering US Sanctions](#)

Synopsis: Trade relations between the US and India has been under strain for some time now and the indications are that it may not improve in the near future. Different trade organisations in the US have asked the US government to designate India as a Priority Foreign Country in its annual review of countries on the ground that India denies adequate and effective protection of intellectual property rights. Such pressures on the US government may end up in an investigation under the Trade Act which could ultimately lead to sanctions on India. The US International Trade Commission has also been

instructed by Congressional leaders to investigate India's industrial policies that discriminate against US imports and investments for supporting Indian domestic industries. Perhaps, an issue of great concern for the American business is the flexibilities existing in Indian patent law intended to promote greater access to generic medicines. India will not tolerate such a move from Washington and will not cooperate with the US on any sort of investigation on Indian IPR or trade laws. The government of India earlier made it clear to the world that more compulsory licenses may be issued under the amended Indian Patents Act for manufacture of patented pharmaceutical products if the drug is considered unaffordable to majority of people. The TRIPS agreement allows a country to issue compulsory licence without the consent of the innovator if it is in public interest. In case the US contemplates to impose sanctions on India, the government of India will have to take the dispute to the WTO.

Clinical Trials

Publication: The Times of India

Edition: Online

Date: May 20, 2014

Headline: [Can pharma-funded trials on efficacy of their medicines be unbiased?](#)

Synopsis: On International Clinical Trials Day observed on May 20, voices questioning the wisdom of letting pharmaceutical companies conduct trials to test the efficacy of medicines that will bring them millions, if not billions, of dollars of profit are gaining in strength. If it is not acceptable that politicians count their own votes on the grounds that they might not be objective enough, then industry being allowed to demonstrate the efficacy of their own products also ought to be unacceptable. This was the argument put forth in a recent paper on biased clinical trials in which the authors stated that patients are probably being given less effective, harmful and more expensive treatments as a result of industry-sponsored evidence being incomplete and biased.

Publication: The Hindustan Times

Edition: Mumbai

Date: May 21, 2014

Headline: [New regulations hit clinical trials in India: Researchers \(link unavailable, scan attached\)](#)

Synopsis: Researchers and doctors said that new regulations have made it increasingly difficult to conduct clinical trials in India. While there is a need for a robust supervising mechanism, new regulations have made it difficult to test treatments and drugs. This does more harm than good to medical science and more so to patients.

Publication: The Times of India

Edition: Mumbai

Date: May 21, 2014

Headline: [No clarity on clinical trial compensation, say doctors and researchers](#)

Synopsis: The Union health department's newly amended guidelines for clinical trials—the exercise of drugs being tried on people before the medicines are given an approval—have failed to bring clarity to the controversy over compensation, say doctors and researchers. Stakeholders have been given 45 days to respond to the amendments in Drugs and Cosmetics Act, which deals with clinical trials. The deadline ends on June 15.

Publication: Afternoon Dispatch & Courier

Edition: Mumbai

Date: May 21, 2014

Headline: [Breaking down clinical trials \(link unavailable, scan attached\)](#)

Synopsis: At the roundtable discussion in recognition of International Clinical Trials Day yesterday, a group of the city's top doctors opined that the rules and standards for being able to conduct clinical trials need to be stringent, but not so stringent that it deters people from conducting trials in the country,

with reference to the new rules brought in by the Drugs Controller General of India (DCGI).

Publication: The Times of India

Edition: Online

Date: May 20, 2014

Headline: [International Clinical Trials Day observed on May 20](#)

Synopsis: As people get together to celebrate International Clinical Trials Day on May 20, the Indian Society for Clinical Research has dedicated the day to patients and particularly to patients who have participated in clinical trials and because of whom there is access to better and newer medicines. "Patients First is ISCR's theme for International Clinical Trials Day 2014," said Suneela Thatte, President, Indian Society for Clinical Research (ISCR).

Website: Pharmabiz

Edition: Online

Date: May 21, 2014

Headline: [Health ministry affirms 157 controversial trial proposals re-evaluated on risks, safety parameters](#)

Synopsis: The Union health ministry has affirmed that the 157 controversial clinical trials, whose review was ordered by the Supreme Court, were reexamined and cleared by the high-level apex and technical committees in accordance with the procedures and direction by the court. The apex committee, headed by the health secretary to monitor the clinical trials sector, has also decided that the existing system would continue with regard to the procedure of clearing proposals of clinical trials of new chemical entities.

Modi led government - Focus on policies: Industry suggestions/ recommendations

Publication: Business Standard

Edition: National

Date: May 21, 2014

Headline: ['Healthy' signs excite experts](#)

Synopsis: Industry, policymakers and public health groups are enthused that the Bharatiya Janata Party (BJP)'s election manifesto has focused on some key sectoral issues. The manifesto talks of streamlining government departments in the sector, the possibility of an "overarching lean body" as regulator, a comprehensive healthcare policy to bring down out-of-pocket expenditure and the need for radical reforms of the National Rural Health Mission (NRHM).

Publication: Mail Today

Edition: Online

Date: May 21, 2014

Headline: [Modi must cut away red tape on science](#)

Synopsis: With the new government formally taking office in Delhi next Monday, one hopes that this change of guard will also bring about some structural changes. Like the vast array of economic and social ministries, we have a large and unwieldy infrastructure relating to science and technology. The election manifesto of the Bharatiya Janata Party devotes a couple of pages on science, technology and innovation, laying down broad contours of the way forward.

Drug pricing

Publication: Deccan Chronicle

Edition: National

Date: May 21, 2014

Headline: [89 cases against drug firms](#)

Synopsis: The National Pharmaceutical Pricing Policy Authority has booked 89 cases against various pharmaceutical companies in violation of the Drug Price Control Order in the country. The companies have been slapped with a fine of Rs 105 crore as they are overcharging for the medicines that are controlled under the DPCO order 2013.

Website: Pharmabiz

Edition: Online

Date: May 21, 2014

Headline: [FDA asks DCGI to initiate measures to make paracetamol syrup 125 mg available in Maharashtra](#)

Synopsis: The Maharashtra Food and Drug Administration (FDA) has asked the union health ministry to initiate immediate measures to make paracetamol syrup 125 mg available in the market across Maharashtra as the manufacturers have stopped manufacturing it as it has impacted their profitability due to it being regulated under the new DPCO. According to sources, the Maharashtra FDA has asked both the Drug Controller General of India (DCGI) and the national drug price controller National Pharmaceutical Pricing Authority (NPPA) to immediately intervene in the matter as the state is facing severe shortage of Paracetamol syrup 125 mg.

Website: Reuters

Edition: Online

Date: May 21, 2014

Headline: [U.S. health insurers say Gilead hepatitis C drug too costly](#)

Synopsis: The leading U.S. health insurance trade group on Tuesday hit out at the extremely high cost of new specialty medicines, accusing drugmakers of taking advantage of the insurance system by pricing products at unsustainable levels. The latest salvo in the war on escalating U.S. healthcare costs came from AHIP - America's Health Insurance Plans - and targeted Sovaldi, the new \$84,000 hepatitis C treatment from Gilead Sciences Inc. John Castellani, chief executive of PhRMA, the leading pharmaceutical industry trade group, said the problem is an insurance system that pushes too much of the cost of treatment onto the patient with high co-pays and deductibles for drugs. "The insurance model makes medicine seem like the most expensive part of the healthcare system," Castellani said.

General Industry

Publication: Deccan Herald

Edition: National

Date: May 21, 2014

Headline: [Growing concern over cases of hospital-acquired infections](#)

Synopsis: Often considered a negative fallout of modern medical care, Hospital- Acquired Infections (HAI) are rarely highlighted but remain an ever-present danger for patients and an enormous challenge for hospitals today. Also called Nosocomial infections, HAI refers to an infection not present in the patient at the time of admission into hospital but which begins two or more days later. Depending on the condition of patient, this infection increases morbidity, requires additional treatment and extends hospital stay, even proving fatal in some cases.

Publication: The Economic Times

Edition: National

Date: May 21, 2014

Headline: [US Food and Drug Administration continues ban on Sun Pharma's Gujarat plant](#)

Synopsis: The US Food and Drug Administration has continued its import ban on Sun Pharma's Karkhadi plant in Gujarat. The US drug regulator had issued a warning letter to Sun Pharma in March

this year for not complying with the goods manufacturing norms practice. However, the recent inspection by the FDA found that Sun Pharma has not plugged the gaps which was raised while issuing the warning letter.

Similar reports in-

Mint- [FDA says Sun Pharma hasn't fixed issues in Gujarat plant](#)

Business Standard- [US FDA not happy with Sun Pharma response](#)

The Financial Express- [Sun Pharma response to import ban inadequate: FDA](#)

NDTV- [Sun Pharma Response to Import Ban Inadequate: US Drug Regulator](#)