



News Updates: April 22, 2014

OPPI

Publication: Express Pharma

Edition: National

Date: April 16- 30, 2014 issue

Headline: ['A healthier India will be a more productive India'](#)

Synopsis: The Organisation of Pharmaceutical Producers of India (OPPI) represents the research-driven pharmaceutical companies in India and is committed to working with the Indian Government to meet the nation's healthcare challenges and find innovative solutions to address those challenges. OPPI looks forward to making a significant contribution by partnering with the Indian Government and other stakeholders to find sustainable solutions to increase healthcare access in India. A holistic approach, that balances the need for innovation with the necessity for more accessible medicines within a robust IP environment, is needed to re-vitalise the Indian pharma industry. On behalf of the research-driven pharma industry, OPPI proposes policy recommendations for the Government's consideration.

Patents/ Compulsory Licensing/ Intellectual Property

Publication: The Times of India

Edition: National

Date: April 22, 2014

Headline: [India may drag US to WTO over unilateral IPR action](#)

Synopsis: India will drag the US to the WTO if Washington decides to put New Delhi in the "Priority Foreign Country" list for intellectual property rights (IPR), which could lead to trade curbs on domestic firms, sources said. This was decided at a high-level meeting called by cabinet secretary Ajit Seth to discuss problems related to IPR issues with the US, especially in the pharmaceutical sector. "Indian IPR laws are fully compliant with WTO and other international norms. Any unilateral action taken by the US will be violative of WTO and India will suitably respond by dragging the US to WTO's dispute resolution mechanism," sources said.

Similar reports in-

The Economic Times- [India not to dilute IPR law; dialogue with pharma cos to continue](#)

Business Standard- [Govt prepares to battle US pressure on patents](#)

The Financial Express- [India may drag US to WTO in case of unilateral IPR action](#)

The Financial Chronicle- India may drag US to WTO in case of unilateral IPR action (link unavailable, scan attached)

Clinical Trials

Publication: Business Standard

Edition: National

Date: April 22, 2014

Headline: [Government must facilitate compensation for clinical trial victims: SC](#)

Synopsis: Expressing concern over the plight of seriously-affected patients of the clinical trials of new chemical entities, the Supreme Court Monday asked the government to "compel" the sponsor companies of such trials to pay compensation to such patients. "Why don't you (government) compel the sponsor (of clinical trials) to pay compensation to people who are seriously affected. They may have suffered more than death (during clinical trials)," said a bench of Justice R.M.Lodha and Justice

Kurian Joseph.

Similar reports in-

The Economic Times- [Volunteers put off by camera consent for clinical trials](#)

The Times of India- [Why seriously affected clinical trial patients not compensated? Supreme Court asks](#)

The Financial Express- [SC tells govt to ensure sponsor compensates clinical trial patients](#)

Deccan Chronicle- [Ensure safety of humans, Supreme Court tells drug cos](#)

The New Indian Express- [No Excuse for Using Poor Women as Guinea Pigs](#)

FDI (pharma)

Publication: The Economic Times

Edition: National

Date: April 22, 2014

Headline: [Non-compete clause for FDI in pharmaceutical companies will not be applicable: Reserve Bank of India](#)

Synopsis: The Reserve Bank today said the non-compete clause will not be applicable in acquisition of existing pharma companies by foreign entities or investors except in certain special cases. India allows 100 per cent FDI in pharma sector. While FDI is permitted through automatic route in case of greenfield investment or new venture, government approval is required in case of brownfield or existing companies.

Similar reports in-

Mint- [RBI says no to non-compete clause in pharma FDIs](#)

Business Standard- [No non-competition clause in pharma FDI: RBI](#)

The Hindu- [No non-compete clause in case of FDI in pharma deals](#)

The Financial Express- [No non-compete clause in pharma FDI](#)

Deccan Chronicle- [Pharma deals can't have non-compete clause: Reserve Bank of India](#)

Drug pricing

Publication: The Times of India

Edition: National

Date: April 22, 2014

Headline: [Glaxo to cut price of Crocin by 50%](#)

Synopsis: GlaxoSmithKline has decided to slash the price of the widely-used fever and pain-relief pill, Crocin Advance by half, after the drug pricing regulator National Pharmaceuticals Pricing Authority (NPPA) rejected its application seeking an exemption from price control. GSK is reducing the price of 'Crocin Advance' to conform to the price notified under Drug Price Control Order (DPCO) 2013 with immediate effect.

FDA

Publication: The Indian Express

Edition: Mumbai

Date: April 22, 2014

Headline: [HC backs govt insistence on USFDA clearance for stents \(link unavailable, scan attached\)](#)

Synopsis: The Bombay High Court on Monday dismissed a petition filed by M/s Vascular Concepts Limited (VCL), a company whose bid for supplying coronary stents to government hospitals under the Rajiv Gandhi Aarogya Yojana (RGAY), was rejected. The company had moved court stating that the state government had questioned the primacy of the Drugs Controller General of India (DCGI) by insisting on USFDA and CE certification (mandatory for products from the European economic area)

for the supply of stents that would be used for coronary ailments in the low-income group covered by the RGAY.

General Industry

Publication: Mumbai Mirror

Edition: Mumbai

Date: April 22, 2014

Headline: [Are generic drugs safe?](#)

Synopsis: The pharmaceutical industry spends an enormous sum of money on the research and development of new drugs every year. Sometimes it is even more than \$350 million per drug that comes to market. Some estimate that as much as 95 percent of the new medicines tested do not see the light of the day because of ineffectiveness and safety concerns. With such large sum of money at stake, altruism has been thrown of the wind.

Publication: Daily News & Analysis

Edition: National

Date: April 22, 2014

Headline: [Vietnam declares war on Indian pharma companies](#)

Synopsis: Vietnam has banned atleast 45 Indian pharmaceutical companies from supplying medicines to its markets. Major players such as Strides Arcolab Ltd, Medley Pharmaceuticals Ltd, Marck Biosciences Ltd, Marksans Pharma Ltd and Umedica Laboratories Pvt Ltd are in the list. Finding the drugs of these companies not of standard quality (NSQ), the Drug Administration of Vietnam (DAV) banned them, DNA has with it a list of erring companies that failed DAV quality tests between January 1, 2011 and October 25,2013.