OPPI News Updates: February 27, 2014

OPPI
Publication: Express Pharma **Edition: National** **Date: February 16-28, 2014 issue** **Headline: 'Nurturing the Industry'** **Synopsis:** The Indian pharmaceutical industry has carved its niche in both the markets, domestic as well as international with its expertise in high end IT and cutting edge science technology. India has strong research and development (R&D) pipeline, maximum number of US FDA approved manufacturing sites outside the US, low R&D costs, innovative scientific manpower with low cost availability which has attracted multinational pharma companies to invest in India. The country's emergence as an important manufacturing base, as well as a market for the global pharma industry, makes India an attractive sector for young professionals in a wide range of specialities involving drug development, marketing, project management and technology. Ranjana Smetacek, Director General, Organisation of Pharmaceutical Producers of India (OPPI) emphasises, "The pharma industry needs to retain and nurture existing talent and equip young workers with the skills and knowledge necessary for better understanding of emerging challenges and opportunities to cultivate a strong image of an employer of choice."
Publication: Express Pharma **Edition: National** **Date: February 16-28, 2014 issue** **Headline: 'Hopeful that the government will consider favourable economic policies and fiscal measures in the 2014-15 budget'** **Synopsis:** The Organisation of Pharmaceutical Producers of India (OPPI) acknowledges the efforts of the Government of India in partnering with the pharma industry towards making medicines more accessible and affordable. As an industry, we are hopeful that the government will consider favourable economic policies and fiscal measures in the 2014-15 budget. There are five key areas where the government can play a key role and promote an environment that is conducive to the growth of the industry while also overcoming healthcare challenges- Healthcare infrastructure building, Improving access to medicines, Reduction in transaction costs, Incentivising R&D and Reduction in tax burden. The OPPI member companies expect that the government will take measures to make all imported lifesaving drugs more affordable to the patients by eliminating the import duty.
Publication: Business Today **Edition: National** **Date: March 16, 2014 issue** **Headline: Intensive Scare** **Synopsis:** The US regulators increased scrutiny of Indian drug exporters is giving the pharmaceutical industry the jitters. Shailesh Ayyangar, Managing Director of drug maker Sanofi India, Vice President - South Asia, Sanofi, and President of the Organisation of Pharmaceutical Producers of India (OPPI), a group of largely multinational drug companies, says: "Lets face it. We are not in a sellers market. We are in a buyers market, and the buyer - lets say, for arguments sake, the US - has the right to decide what quality standards it wants from the second largest exporter of generics to the US. It is therefore in our interest to ask the right questions, get the consultants to help us with systems and processes." He notes that many companies are getting nervous today because a lot of questions are being asked, and adds that regulators face flak in their own countries if they approve products that turn out substandard.

Patents/Compulsory Licensing/Intellectual Property

Website: NDTV
Edition: Online
Date: February 26, 2014
Headline: India, US row over trade policies, intellectual property rights likely to worsen

Synopsis: After a furious India decided to block investigations by US authorities into its trade policies and patent laws, New York could label India as a "Priority Foreign Country", a tag it gives to worst offenders of intellectual property rights. The accusation could lead to trade sanctions and escalate the already-strained tension between the two countries. The suggestion to designate India a Priority Foreign Country was given to the US Trade Representative's (USTR) office by the National Association of Manufacturers (NAM), which represents about 50 US business groups. "We have not seen any progress. What we keep hearing from the Indian side is that they don't want to talk about these things and that starts to narrow the range of options that we have to address the issue in a constructive manner," Chris Moore, Senior Director at NAM told NDTV.

Drug Pricing/ Access

Publication: The Times Of India
Edition: National
Date: February 27, 2014
Headline: Free medicines to all in Maharashtra

Synopsis: Citizens irrespective of income can walk into any public health centre or hospital and demand medicines. There is no need for a prescription, announced chief minister Prithviraj Chavan in the Maharashtra legislature. The scheme will come into force from March 1. It will annually cost the government Rs 510 crore. The cost will be borne jointly by the centre and the state. A list of 429 drugs and 107 instruments to be made available to citizens has been drawn up by the public health department. Opposition legislators staged a walkout to protest the non-inclusion of the scheme in the budget.

Publication: Pharmabiz
Edition: Online
Date: February 27, 2014
Headline: DoP rejects review petitions of several cos including Albert David, Baxter, etc.

Synopsis: The Department of Pharmaceuticals (DoP) has rejected the review petitions filed by several companies including Albert David, Baxter (India), Indi Pharma, Gland Pharma, etc. against the ceiling of prices fixed by the NPPA on their products. Albert David had filed the review application under para 31 of DPCO, 2013 against the NPPA notification S.O. NO. 1819(E) dated 21st June, 2013 fixing ceiling price of scheduled medicine Glucose Injection 10 per cent.

Publication: The Hindu
Edition: Kochi
Date: February 27, 2014
Headline: Maximum price of drugs fixed (link unavailable, scan attached)

Synopsis: The National Pharmaceutical Pricing Authority (NPPA) has fixed the maximum price of 431 drugs, excluding sales tax.

Publication: Fierce Pharma
Edition: Online
Date: February 26, 2014
Headline: Pharma fights back against proposed changes to Medicare drug spending

Synopsis: When the Medicare Part D program was launched a decade ago, seniors were guaranteed low-cost access to drugs in six broad treatment categories. But if recently proposed changes to the program are implemented, two of those drug classes will no longer be automatically covered--antidepressants and immunosuppressants used in organ transplants.

Clinical Trials

Publication: The Hindu Business Line
Edition: National
Date: February 27, 2014
Headline: Regulatory delays sending clinical trials abroad

Synopsis: Delays in permissions and regulatory clearances are resulting in companies taking clinical trials abroad, said Dilip Shanghvi, Chairman and Managing Director of Sun Pharma Advanced Research Company (SPARC), even as the company unveiled its research line-up and plans to license out some of its prospective products.
The first and second phase of clinical trials on several of SPARC's products are being done overseas, Shanghvi said, responding to a query on the domestic clinical trial environment.

Publication: Pharmabiz
Edition: National
Date: February 27, 2014
Headline: Novartis extends leadership in clinical trial data transparency

Synopsis: Novartis has introduced additional steps to extend its leadership in clinical trial data transparency. Since 2005, and before requirements were in place, Novartis has been voluntarily disclosing summaries of Clinical Study Reports of its innovative medicines on its own website (http://www.novctrd.com). In addition, the company is committed to enhancing Clinical Study Report summaries for all new pivotal studies to include easy to understand consumer language summaries and additional interpretation of data as of the end of 2014.

Publication: Outlook Business
Edition: National
Date: February 15- March 01, 2014 edition
Headline: Critical condition (scans attached as well)

Synopsis: Pharma companies are moving clinical trials out of India as the government imposes new, stricter regulations and delays approvals. Is this the end of the road for a sunshine sector?

FDA/Drug Regulation

Publication: The Financial Express
Edition: National
Date: February 27, 2014
Headline: Ranbaxy Laboratories whistleblower: Downgrade pharma industry till India gets its act together

Synopsis: Dinesh Thakur, former Ranbaxy Laboratories Ltd executive who blew the whistle on manufacturing malpractices at the company, has hinted that an effective approach to enforce quality drug manufacturing and export from India would be to downgrade the domestic pharma industry and prevent it from exporting to US till regulators and companies get their act together.
In a working paper titled 'India's drug quality under the spotlight with FDA visit,' Thakur says that "if India wants its companies to export to US, then it should finance and equip its inspectors properly so as to build a cadre of talented, professional inspectors".

Similar report in-

The Economic Times- Ranbaxy whistleblower shares his experiences with US lawmakers

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Publication: Business Standard
Edition: National
Date: February 27, 2014
Headline: Made-in-India drugs to be in dock at Capitol Hill

Synopsis: The concerns surrounding drug manufacturing practices in India appear to have reached foreign shores, beyond the international regulators' domain. Ranbaxy whistle-blower Dinesh Thakur, along with a group of medical academicians and researchers, is set to address the US Congressional staff (of American legislators) on Wednesday at an event at Capitol Hill in Washington. The group is expected to raise issues about the quality of medicines available in the US, primarily those imported from India. Apart from Thakur, the panelists for the much-hyped event include Amir Attaran, a professor of law and medicine at the University of Ottawa, Harry Lever, a senior cardiologist at the Cleveland Clinic and Preston Mason, a member of the cardiovascular division at Brigham and Women's Hospital and Harvard Medical School. The event will be moderated by Roger Bate, an expert on substandard and falsified medicines.

Publication: Business Standard
Editions: Delhi, Bangalore, Kolkata
Date: February 27, 2014
Headline: DIPP team to see major overhaul (link unavailable, scan attached)

Synopsis: The Department of Industrial Policy and Promotion's (DIPP) team, instrumental in changing the country's foreign direct investment (FDI) landscape and having moved some of the most controversial decisions in recent times, will undergo an overhaul. Saurabh Chandra, secretary of DIPP since April 2012, oversaw some of the most important FDI decisions. The most significant was allowing FDI up to 51 per cent in multi- brand retail trading (MBRT).

Publication: The Economic Times
Edition: National
Date: February 27, 2014
Headline: Lupin gets USFDA nod for generic version of Mycobutin Capsules

Synopsis: Pharmaceutical firm Lupin today said it has received final approval from US health regulator to market the generic version of Mycobutin capsules of Pharmacia and Upjohn Company that are used while treating advance HIV infection. The approval from the US Food and Drug Administration is for Rifabutin Capsules USP, in strength of 150 mg, said Lupin in a statement.

Publication: Firstpost
Edition: Online
Date: February 27, 2014
Headline: Why India would do well to heed US advice on drug safety

Synopsis: Food and Drug Administration Commissioner Margaret Hamburg wrapped up an eight day trip to India aimed at keeping substandard drugs from entering the US. Hamburg and ministry officials signed a statement of intent to improve regulatory practice and improve drug safety and quality, but there are daunting obstacles. To begin with India's Central Drugs Standard Control Organisation (CDSCO), the country's drug regulator, has a staff of 323, barely 2 percent the size of the FDA's. Its authority is limited to new drugs, while it falls on state health departments to oversee the making of medicines that have been on the market at least four years.

Publication: Deccan Herald
Edition: National
Date: February 27, 2014
Headline: Drug Control dept grapples with staff shortage

Synopsis: Severe staff shortage in the Drug Control department has had a crippling effect on its administrative functions. The department has not been able to conduct regular inspections of pharmacies across the State even as complaints about sale of spurious and substandard drugs have been piling up. For a State that has more than 28,000 wholesale and retail pharmacies, there are just 49 drug inspectors who are required to perform numerous duties.

General Industry

Publication: Business Standard
Edition: National
Date: February 27, 2014
OPED by T S Vishwanath
Headline: Back to the unfinished agenda

Synopsis: As the dust settles on the Bali deal of the World Trade Organisation (WTO) and member countries get back to the negotiating rooms in Geneva to operationalise the Bali agreements and decisions, and also take the Doha Round of negotiations forward, the focus is shifting to the unfinished agenda of the Round that was launched in 2001 and the possible way forward. To begin with, negotiators need to quickly finalise the list of issues that they would want to be addressed immediately. Prioritisation of issues will help negotiators realise how easy or difficult it would be to conclude the Round. Importantly, there will be an urgent need to balance the priorities among the developed, developing and least developed country members.

Publication: Business Standard- The Smart Investor
Edition: National
Date: February 27, 2014
Headline: US sales rebound a boost for Cadila

Synopsis: The Cadila Healthcare stock has been gaining since November 2013, hitting an all-time high of Rs 1,022 on Tuesday, before closing at Rs 999. The rise can be attributed to the company's improving prospects in the US business, led by a series of Food and Drug Administration (FDA) approvals for generic launches, including the one for clonidine HCl injections, an analgesic used to provide relief from severe pain. The stock's recent performance is in contrast to the underperformance against the Sensex during the first half of 2013-14, owing to the slow rate of approvals from the US FDA and muted domestic sales growth, hit by the NLEM (New List of Essential Medicines).

Website: CNBC
Edition: Online
Date: February 26, 2014
Headline: Pharma offering new hope for hepatitis C patients

Synopsis: Bristol-Myers Squibb has gotten a lot of attention lately for its new cancer treatments. The so-called bio-pharma player has been a pioneer in immuno-oncology, recently taking steps to further expand the business. But for all of the attention paid to its cancer drug pipeline, Bristol just scored a breakthrough therapy designation from the Food and Drug Administration for a treatment that targets hepatitis C.