News Updates: January 14, 2014

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Financial Express
Edition: New Delhi
Date: January 14, 2014
Headline: Cadila Pharma & NovaSAID join hands to develop drug

Synopsis: Swedish research company NovaSAID AB, part of Karolinska Development's portfolio, and Cadila Pharmaceuticals, a leading pharma company in IndiaSwedish research company NovaSAID AB, part of Karolinska Development's portfolio, and Cadila Pharmaceuticals, a leading pharma company in India, have entered into a strategic partnership to develop treatment for inflammation and pain in conditions such as rheumatoid arthritis. According to a statement issued by Cadila Pharmaceuticals, the companies will work on pre-clinical and clinical development of drug candidates that have been developed by NovaSAID and the development will be conducted at Cadila Pharmaceuticals' facility in Ahmedabad.

FDI

Publication: The Hindu Business Line
Edition: National
Date: January 14, 2014
Headline: FIPB okays GSK's Rs 6,400-crore investment, highest in pharma sector

Synopsis: The Foreign Investment Promotion Board (FIPB) has cleared UK-based pharma major GlaxoSmithKline's (GSK) proposal to invest Rs 6,400 crore in its Indian arm to raise its stake in the company. The FIPB, headed by Department of Economic Affairs (DEA) Secretary Arvind Mayaram, also cleared a proposal by Singapore-based pharma company Hospira to bring Rs 1,039 crore into its India operations. An FDI proposal by Japanese company Hitachi to bring in investments worth Rs 1,540 crore got the green signal too. Pharma major Lupin's FDI proposal, however, was not cleared by the FIPB on Monday.

Clinical Trials

Publication: The Times of India
Edition: Bangalore
Journalist: Saswati Mukherjee
Date: January 14, 2014
Headline: India must become an active centre for ethical clinical research: Professor Ranjit Roy Chaudhury

Synopsis: "India must become an active centre for ethical clinical research and 'Health India' which emphasizes a collaborative approach by all disciplines of medicine should be our vision," said distinguished academician and clinical pharmacologist, Padmashree Prof Ranjit Roy Chaudhury, speaking as guest of honour at 'Research at Crossroads', the 7th Annual Conference being held by Indian Society of clinical research in Bangalore recently. Chaudhury shared the fundamental features of his report 'Professor Ranjit Roy Chaudhury Expert Committee to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs'. Underlying the recommendations was the need to ensure a fair, transparent and honest framework that would build credibility for clinical research amongst the public.

Publication: Pharmabiz
Edition: Online
Journalist: Nandita Vijay

Date: January 14, 2014
Headline: India would be the first country to accredit principal investigators in clinical trials: Dr Rebecca Li

Synopsis: India will be the first country to accredit its principal investigators going by the recent regulations on mandating the need to audit and approve its qualified clinical research teams, said Dr Rebecca Li, executive director, Multi Regional Centre for Clinical Trials (MRCT) Centre at Harvard. Dr Li, who was an invitee to the 7th Annual ISCR event, said that regulations in clinical research would catapult the country to the next level of growth in trials. However, she sympathized with Indian clinical research industry on the current state of affairs but indicated that a similar situation prevailed in the European Union between 2007 and 2011. The best part of the crisis is that it would lead to a set of regulations which would then lead India to regain much of its lost glory. We need to understand that the intentions behind such new norms and changes will be good but the high risk drug industry does not like is uncertainty, she added.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Times of India
Edition: National
Journalist: Rupali Mukherjee
Date: January 14, 2014
Headline: USFDA red flags Ranbaxy's 4th plant

Synopsis: Fresh trouble seems to be brewing for Ranbaxy with the US regulatory agency Food and Drug Administration (USFDA) expressing concern at the quality and manufacturing standards of the company's plant at Toansa (Punjab), bringing its lone facility outside the FDA glare under the scanner and thereby compounding woes for the pharmaceutical major. The USFDA issued a Form 483 after completing an inspection on Saturday of the Toansa facility which manufactures mainly active pharmaceutical ingredients (raw materials) for the US and domestic market. With the latest regulatory salvo against Toansa, all facilities of the company are now under the USFDA scanner, casting doubts on the company's ability in improving its quality standards even after paying a harsh penalty and losing considerable brand equity.

Publication: Business Standard
Edition: National
Date: January 14, 2014
Headline: FDA notice to Ranbaxy for violations at Punjab plant

Synopsis: Troubles seems to be far from over for drug maker Ranbaxy Laboratories. The company’s active pharmaceutical ingredient (API) manufacturing factory in Punjab’s Toansa has received a Form 483 warning from the US Food and Drug Administration (US FDA), raising concerns over manufacturing practices. The move is significant because the Toansa facility, which supplies 70-75 per cent of the pharmaceutical ingredients, is Ranbaxy’s main API factory. Though there is no restriction on supplies from this facility to the US at present, failure to address the concerns raised by US FDA could lead to a ban on all US exports from this factory. The US drug regulator had inspected the facility last week.

Also appeared in **Financial Chronicle:** FDA raises red flag on a fifth Ranbaxy facility

Publication: Mint
Edition: New Delhi
Journalist: C.H. Unnikrishnan
Date: January 14, 2014
Headline: Ranbaxy shares dive over 5% on fresh FDA scrutiny

Synopsis: The US FDA cited quality compliance issues at Ranbaxy’s API plant in Toansa, Punjab. Shares of Ranbaxy Laboratories Ltd fell as much as 9.4% on BSE on Monday after the US Food and Drug Administration (FDA) cited quality compliance issues at the company’s active pharmaceutical ingredients (API) plant in Toansa, Punjab. The stock, however, recovered to close at Rs.438.35, down 5.42%, on Monday on BSE while the benchmark Sensex rose 1.81% to close at 21,134.21 points.

Publication: Reuters
Edition: Online
Date: January 14, 2014
Headline: **Merck's anti-blood clot drug should be approved: FDA review**

Synopsis: Merck & Co Inc's experimental blood clot-preventing drug vorapaxar should be approved, based on "robustly positive" clinical trial results, according to a preliminary review of the data by the U.S. Food and Drug Administration. The review, posted on the FDA's website on Monday, comes two days ahead of a meeting of outside medical experts who are expected to recommend whether it should be approved. The FDA usually follows the advice of its advisory panels. The drug, which would be sold under the brand name Zontivity, is designed to prevent heart-related deaths, cardiac arrests and strokes in patients who have had a recent heart attack. It would not be recommended for patients who have previously had a stroke because of an increased risk of bleeding in the brain.

General Industry

Publication: The Economic Times
Edition: National
Date: January 14, 2014
Headline: **Zoher Sihorwala to head Wockhardt's regulatory unit**

Synopsis: Mumbai-based pharmaceutical company Wockhardt has appointed Zoher Sihorwala to head its regulatory and compliance division, a senior executive said. Sihorwala comes from Dr Reddy's, India's second-biggest drug maker, where he was vice-president of global regulatory affairs. The appointment comes at a time when Wockhardt is facing the heat from drug regulatory authorities in the US and the UK over quality issues.

Publication: Business Standard
Edition: Chennai
Date: January 14, 2014
Headline: **Pharma volumes up 8.2 per cent in December**

Synopsis: The Indian pharmaceutical market saw a volume growth of 8.2 per cent year-on-year and a business turnover of Rs 6,256 crore in Dec 2013, according to a report from AIOCD Pharmasofttech AWACS, a pharmaceutical market research company. The price controlled drugs market saw a 8.5 per cent fall in volumes, in which the portfolio of Glaxo SmithKline and Ranbaxy had the highest fall, while Sun Pharma had the least impact. “The December 2013 growth driver split shows positive on the parameter of volume and new introductions, leading to an overall positive growth when compared with December 2012,” said the report.

Publication: Mint (Interview)
Edition: New Delhi
Journalist: Mini Menon
Date: January 14, 2014
Headline: Lupin expects to launch 25-30 products every year (No online Link available)

Synopsis: Pharmaceutical company Lupin Ltd will look to launch 25 – 30 products every year, with a focus on obtaining marketing exclusivity in the US by being among the first to file for regulatory approvals for its generic drugs, managing Director Nitesh Gupta said in this interview. He also spoke extensively on Lupin’s acquisitions strategy.

Publication: The Times of India
Edition: National
Date: January 14, 2014

Headline: Maharashtra govt agrees to simplify kidney transplant process

Synopsis: A month after leader of Opposition Eknath Khadse asked the chief minister to stop red tapism in kidney transplant, the public health department on Monday agreed in principle to simplify the procedure.

Publication: The Hindu
Edition: National
Journalist: Aarti Dhar
Date: January 14, 2014
Headline: Purse-friendly diabetic testing kits launched

Synopsis: Indigenous glucometer, strip will be available in 6 months. Bringing relief to millions of diabetics who spend a substantial amount of their earnings on testing their blood glucose level, the Health Ministry on Monday launched indigenous, affordable testing kits. The launching of two kinds of glucometers and testing strips will make mass screening and detection feasible. The glucometers will now cost between Rs. 500 and 1,000 as against the price of Rs. 1,000-2,500 for the imported instrument. Each glucostrip will cost between Rs. 2 and Rs. 4, down from Rs. 18-35. The diabetes screening system and test strips have been developed by the Indian Institute of Technology Mumbai (called Suchek) and the Birla Institute of Technology, Hyderabad (known as QuickcheQ) with funding from the Indian Council of Medical Research. These will be manufactured by Biosense Technologies and will be available in the open market in the next six months.

Publication: The Asian Age
Edition: New Delhi
Journalist: Teena Thacker
Date: January 14, 2014
Headline: Indigenous, cheap, quick test for diabetes

Synopsis: All pregnant women in India will be tested for gestational diabetes at the health sub centres free of cost. With focus on reducing maternal complication and neo-natal deaths, the government on Monday said that pregnant women would be provided the facility for blood sugar test.The low-cost indigenous blood sugar testing strips that would cost as little as `2-5 and glucomotre at `500-800 as against `1,000-2,500 launched by Union health minister on Monday will be used for the purpose. Around three crore women in India get pregnant every year. While, they are tested for other diseases like hypertension during their periodic check up, but due to high cost of glucomotre and blood testing strips, diabetes testing was never thought would be feasible for testing. With the launch of low cost strips and glucomotre, officials say the problem has been solved. “The timely testing will help reduce the complications during pregnancy and neo natal deaths,” said Anuradha Gupta, additional secretary in the ministry.

Publication: The Indian Express
Edition: National
Date: January 14, 2014
Headline: No case in 3 yrs, India is polio free

Synopsis: India on Monday completed three consecutive years without a single wild polio case being reported from any part of the country, thereby achieving the three-year milestone necessary to achieve polio-free certification from World Health Organisation. The last polio case was reported on January 13, 2011 from Howrah in West Bengal. The official announcement of India becoming a polio free country will be made on February 11. “It is a matter of pride for the nation that not a single case of polio has been detected in the three years. This monumental milestone was made possible due to unwavering political will at the highest levels, commitment of adequate financial resources, technological innovations like the bivalent vaccine and tireless efforts of millions of workers, including more than 23 lakh vaccinators and volunteers, and more than 1.5 lakh supervisors,” Union Health Minister Ghulam Nabi Azad said in Delhi.

Publication: The Pioneer
Edition: New Delhi
Date: January 14, 2014
Headline: Sikkim registers highest rate of diabetic patients

Synopsis: The country is fast coming under the grip of diabetes with around 6 per cent out of five crore people surveyed found to be suffering from the lifestyle disease. Sikkim has higher prevalence of diabetes at 13.62 per cent followed by Gujarat and Punjab at 9 per cent each, as per the ongoing national survey being conducted by the Union Health Ministry. Also, the suspected prevalence of diabetes in urban slums was found to be as high as 11.77 per cent, said Health Minister Ghulam Nabi Azad about the outcome of the screening test being conducted under the national programme on Prevention and Control of Cancer, diabetes, CVDs and Stroke.

Publication: Deccan Herald
Edition: New Delhi
Journalist: Kalyan Ray
Date: January 14, 2014
Headline: Polio eradication certificate laudable, but the endgame is still tricky

Synopsis: Almost 25 years ago, Sam Pitroda, then adviser to the prime minister chaired a meeting in Delhi in which it was decided to produce inactivated poliovirus vaccine (IPV) in India for inoculating children against the crippling disease that infected 500 to 1,000 children daily in the 1970s and 1980s. The vaccine's inventor Jonas Salk convinced the top echelons of Indian government on the importance of going forward with IPV ignoring the Union Health Ministry's choice of oral polio vaccine. Notwithstanding the cost factor – IPV is costlier than oral polio vaccine (OPV) – the government in March, 1988 decided to set up a vaccine manufacturing unit named Indian Vaccine Company Limited (IVCOL) to make IPV as large number of kids were affected and killed by the polio virus. Land was acquired at Manesar, ahead of Gurgaon and French vaccine producer Institut Merieux was roped in.

Publication: The Indian Express
Edition: New Delhi
Journalist: Anuradha Mascarenhas
Date: January 14, 2014
Headline: The cause and effect of Maharashtra's mixed prescription

Synopsis: Maharashtra's decision to allow homeopathic doctors to practise allopathy after a year's training in pharmacology is set to see legal wrangling, apart from sparking an ethical debate. The Indian Medical Association has gone to court against the decision, armed with recent court directives such as last month's judgment of the Allahabad High Court that rules against such short courses to practise modern medicine, and a May 2013 Bombay High Court ruling that stayed a government diktat to amend the schedule of the Maharashtra Medical Council Act to allow allopathic practice by holders of an LCEH (licentiate of the court of examiners in homeopathy) degree.