



News Updates: December 18, 2013

FDI / Foreign Investment in Pharma / M&As in Pharma

Publication: CRN

Edition: Online

Journalist: Amit Singh

Date: December 17, 2013

Headline: [Where The Growth Prospects Are Always Healthy](#)

Synopsis: According to McKinsey, from a market size of \$12.6 billion in 2009, the Indian pharmaceutical industry is expected to grow to \$55 billion by 2020. IT investments in the vertical are growing rapidly due to exports and compliance requirements, as well as FDI inflow and government initiatives. It has been estimated that the industry will spend Rs 1,100 crore on IT in 2014. International standards: Nearly 65 percent of the pharma industry's revenue comes from exports. Most Indian pharma companies are now selling branded drugs and generics in the international market and hence need to meet compliance guidelines. That's driving IT in this vertical, says Tarun Kaura, Director, Technology Sales, India & Saarc, Symantec.

Clinical Trials

Publication: Pharmabiz

Edition: Online (Bangalore)

Date: December 18, 2013

Headline: [StelisBiopharma & Pieris Forge alliance for novel Anticalin therapeutics in ophthalmology](#)

Synopsis: Stelis Biopharma, the erstwhile Agila Biotech, a subsidiary of Strides Arcolab Limited, focused on biotherapeutic drug development and bio-manufacturing, and Pieris AG, a next generation therapeutic protein R&D company, announced the initiation of a long-term collaboration for clinical development and commercialization of multiple novel Anticalin-based protein therapeutics worldwide, primarily focusing on ophthalmology.

Publication: Pharmabiz

Edition: Online (New Delhi)

Date: December 18, 2013

Headline: [Experts call for need of GCP for establishing safety of botanical drugs](#)

Synopsis: Experts have called for good clinical practices (GCP) and stronger regulatory mechanism to establish the safety and efficacy of botanical drugs and ensure wider acceptance to them at the emerging global market. Taking part at a two-day 'Indo-US Symposium on Botanical Drug Development' held near here recently, the experts from both India and abroad also felt that at present the sector was confronting multiple challenges in establishing the safety and efficacy of the herbal drugs.

Publication: Pharmabiz

Edition: Online (New Delhi)

Journalist: Joseph Alexander

Date: December 18, 2013

Headline: [Out of 157 trials approved during 2012, only 64 are in progress, Health Min to SC](#)

Synopsis: Out of the contentious 157 clinical trials suspended by the Supreme Court, only 64 were going on at present, the Union health ministry told the Supreme Court as the ongoing case has been posted for hearing after five weeks, thus continuing the uncertainty over the clinical trial approvals in the country. According to the affidavit submitted by the Ministry in the Apex Court, which took up the case for hearing on Monday, the details

were given only about 148 trials whereas the petitioners sought details of remaining trials and other details.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Economic Times

Edition: Online

Date: December 18, 2013

Headline: [Weak rupee is tempting for foreign investors bringing dollars to India](#)

Synopsis: British pharma giant GlaxoSmithKline Plc (GSK) will spend \$1 billion to raise its stake in its Indian arm, GSK Pharmaceuticals, from 50.7% to 75%. This offer comes after it spent another \$1 billion to increase its shareholding in GSK Consumer Healthcare, a company best known as the maker of Horlicks. The deal follows Unilever's bumper \$3-billion-plus investment to mop up stocks of its Indian arm, Hindustan UnileverBSE 0.11 %, in July.

Publication: Business Standard (also appeared in The Hindu Business Line, The Economic Times)

Edition: Online (Reproduced from PTI)

Date: December 18, 2013

Headline: [US FDA disapproves Sun Pharma arm's anti-depressant](#)

Synopsis: Sun Pharma Advanced Research Company on Tuesday said the US drug regulator had disapproved its new drug application for an anti-depressant in its present form. The US Food and Drug Administration (FDA) has sent a letter seeking additional studies related to the efficacy and safety of its Venlafaxine extended-release 300mg tablets, it said. It said it was in receipt of a complete response letter, a communication from FDA that a new drug application cannot be approved in its present form.

Publication: Financial Chronicle

Edition: Online (Mumbai)

Journalist: Ravi Ranjan Prasad

Date: Dec 17, 2013

Headline: [Pharma shares rally on US FDA approvals](#)

Synopsis: Pharma and healthcare company shares were buzzing on Tuesday on the stock market, with BSE Healthcare index being the biggest index gainer, contrary to the benchmark indices Sensex and Nifty closing in the red. The US FDA approvals brought cheer to some domestic pharma majors which had a brushing effect even on other pharma companies, along with the sentimentally positive news of \$1 billion open offer announced by the promoters of Glaxosmithkline Pharmaceuticals, analysts said.

Publication: The Indian Express

Edition: Online

Contributory article: Prashant Reddy Thikkavarapu

Date: December 18, 2013

Headline: [The safety imperative](#)

Synopsis: Nuclear, biotech and pharma regulatory bills are pending in Parliament. One would expect a country that has witnessed an industrial disaster like the Bhopal gas tragedy to be especially sensitive to the issue of regulating dangerous industries and untested technologies. Unfortunately, India remains a country where the financial markets and telecom markets are better regulated than the nuclear, biotech or pharmaceutical industries.

Publication: The Financial Express

Edition: National

Date: December 18, 2013

Headline: [Still in play](#)

Synopsis: GlaxoSmithKline Plc's intention to mop up as large a stake as possible in its Indian subsidiary, without breaching the listing guidelines, is yet more evidence that MNCs remain convinced India is a key market for them. How important India is as a hunting ground is demonstrated by the fairly hefty premium that Britain's biggest drug maker is willing to fork out for the shares—the offer price of R3,100 apiece discounts the CY14 estimated earnings by close to 38 times. To be sure, \$1 billion is small change for GSK Plc, which, at the end of September 30, 2013, had \$4.5 billion in cash. But an increasing number of MNCs are looking to get a larger share of the India spoils—earlier this year Unilever had committed more than \$5 billion and recently Glaxo announced it would be setting up a plant here at an investment of R864 crore. The return on these investments can be lucrative—the Indian pharma market, which grew at just 10% in FY13, is worth some \$12-12.5 billion today and is poised to double in the next few years. Perhaps MNCs are also hedging themselves, given patents for a host of blockbuster drugs are set to expire by 2017 which would mean smaller revenues for them in their home markets as they lose out to generics.

Publication: Pharmabiz

Edition: Online

Date: December 18, 2013

Headline: [Kerala Pharmacy Council wants state govt to issue drug licenses based on working hours of pharmacists](#)

Synopsis: Kerala State Pharmacy Council (KSPC) has urged the state government to issue an order to the drug control department asking them to release drug licences for retail sales based on the working hours of the pharmacist in the medical stores. The Council has made this demand following reports by pharmacy inspectors that several pharmacies are working without the presence of registered pharmacists, especially during night hours. According to B Rajan, president of the Council, after 6 pm most of the pharmacies are working without pharmacists. The qualified pharmacists are working only for eight hours a day. He said the Council has also written to the union government seeking amendment of Drugs & Cosmetics Act in this regard as the Act also demands a full time registered pharmacist in the drug store.

Patents

Publication: The Indian Express

Edition: Online (Ahmedabad)

Date: December 18, 2013

Headline: [Indian pharma company wins patent war against US firm](#)

Synopsis: Gujarat-based La Renon Healthcare Pvt Ltd has successfully got revoked the Indian patent held by a US firm for a proprietary probiotic formulation, named Renadyl. La Renon had filed a patent revocation plea against the US-based Kibow Biotech before the Intellectual Property Appellate Patent Board, (IPAB), Chennai, which passed its order. IPAB had cited "lack of invention" while upholding the patent revocation plea on November 13, 2013. Kibow Biotech had earlier challenged La Renon in Madras High Court accusing it of infringement of patent rights which it was holding since 2007. A patent battle was on between the two companies since May 2011 when Kibow Biotech sought a restraint order against La Renon to curb competition in the market, according to the La Renon management. It was dismissed in August 2011 due to non-maintainability under Section 599 of the Companies Act. Following this, La Renon filed a plea before IPAB for revocation of the patent in question.

Vaccine

Publication: Pharmabiz

Edition: Online (Mumbai)

Date: December 18, 2013

Headline: [Health ministry confirms 3 deaths due to pentavalent vaccination](#)

Synopsis: Even as the Supreme Court is examining a writ petition seeking to discontinue the manufacture, use and sale of the pentavalent vaccine due to its adverse effects, the union health ministry for the first time has admitted at least three deaths have occurred due to the immunisation of pentavalent vaccine. According to the latest causality assessment report of the national adverse events following immunisation (AEFI) committee, at least three deaths were related to pentavalent immunisation among the 20 such cases investigated by the government. As per the new causality report, only one death has happened due to SIDS (sudden infant death

syndrome)". There are three deaths with causal association with immunisation and seven reported as 'unclassifiable'. Incidentally, all the three deaths due to 'A consistent causal association to immunisation' have been reported from Tamil Nadu.

Publication: The Indian Express

Edition: Online (Mumbai)

Date: December 18, 2013

Headline: [Newly discovered antibodies raise HIV vaccine hopes](#)

Synopsis: Fresh hopes for an HIV/AIDS vaccine have emerged with the discovery of antibodies that can thwart the virus. Imagining a world without AIDS is a distinct possibility, say scientists who were in New Delhi for a two-day scientific group meeting of the International AIDS Vaccine Initiative. Dr Wayne Koff, chief scientific officer in IAVI and a leading figure in the AIDS vaccine research, said scientists have isolated, from HIV-positive donors around the world, a number of antibodies capable of blocking a broad spectrum of HIV variants. Only some infected people produce these antibodies and it takes the body three years to start doing so. Scientists say the vaccine developed has to give people the right kind of HIV protein that "instructs" the body how to make these antibodies.

General Industry

Publication: The Economic Times

Edition: National

Date: December 18, 2013

Headline: [Montek for consultation on PPP in healthcare](#) (Online: [Montek Singh Ahluwalia for consultation on PPP in healthcare](#))

Synopsis: Ahead of the mid-term appraisal of the 12th Plan (2012-17) due next year, the Planning Commission has called for an intensive stakeholder consultation in the healthcare sector to arrive at a consensus on how best to implement public-private partnership projects.

Publication: Reuters

Edition: Online

Journalist: Ben Hirschler

Date: December 18, 2013

Headline: [GSK to stop paying doctors in major marketing overhaul](#)

Synopsis: GlaxoSmithKline will stop paying doctors for promoting its drugs and scrap prescription targets for its marketing staff - a first for an industry battling scandals over its sales practices, and a challenge for its peers to follow suit. Britain's biggest drugmaker also said on Tuesday it would stop payments to healthcare professionals for attending medical conferences as it tries to persuade critics it is addressing conflicts of interest that could put commercial interests ahead of the best outcome for patients. The move may force other companies to act, since the entire drugs industry has been under fire for aggressive marketing tactics in recent years.

Similar reports on the topic have appeared in the following publications

The Economic Times: [GlaxoSmithKline will no longer pay doctors to promote its drugs](#)

The Times of India: [Glaxo to stop paying docs to promote drugs](#)

Mint: [GlaxoSmithKline overhauls sales practices after scandals](#)

The Financial Express: [GlaxoSmithKline to stop paying doctors in major marketing overhaul](#)

The Indian Express: [GSK to stop paying doctors for promoting its drugs](#)

Firstpost: [GSK to stop paying doctors to promote drugs – NY Times](#)

The Telegraph (India): [Glaxo to halt sale payoff - UK giant says it won't pay doctors to promote drugs](#)

The Telegraph (UK): [GSK ends payments to doctors in incentives shake-up](#)

Publication: The Hindu (Opinion)

Edition: Noida/ Delhi

Journalist: Raghuvir Srinivasan

Date: December 18, 2013

Headline: [Time for a 'Right to Healthcare'](#)

Synopsis: Amartya Sen says India ranks alongside Haiti and Sierra Leone when it comes to government spending on health as a share of the total health expenditure of the people. Any self-respecting country has to regard provision of health-care to its citizens a primary responsibility and it's amazing that the Indian government never thought of that, says Amartya Sen, Nobel Laureate and Thomas W. Lamont University Professor, and Professor of Economics and Philosophy at Harvard University. Excerpts from his interview with Raghuvir Srinivasan

Publication: First Post

Edition: Online (*Reproduced from IANS*)

Date: December 18, 2013

Headline: [Dialogue on health should be more participatory: Montek](#)

Synopsis: Dialogue on health should be made more participatory and involve pharmaceutical companies as well as general practitioners and hospitals, Planning Commission Deputy Chairman Montek Singh Ahluwalia said Tuesday. A discussion consisting independent experts and stakeholders in healthcare should be set up for generating ideas for the mid-term appraisal of the 12th five-year plan, due for next year, he said. "There is already a consensus on the priorities that have to be assigned to the health segment but what holds that back is the differences in the perception as to how to go about it and implement them," Ahluwalia said here giving the keynote address at the 10th India Health Summit organised by the Confederation of Indian Industry (CII) and the union health ministry.

Publication: Hindustan Times

Edition: Mumbai

Journalist: Manu P Toms

Date: December 18, 2013

Headline: [MNCs bet on India despite gloom](#)

Synopsis: Several multinationals are betting big on the India growth story despite the growing skepticism about the current business environment and decelerating economic growth. In the last six months, global giants including Anglo-Dutch consumer goods giant Unilever Plc, British telecom major Vodafone and UK-based pharma and consumer healthcare company GSK have made open offers for raising their stakes in their Indian subsidiaries by investing billions of dollars. "We have been here for many years and we are used to fluctuations in India. We take a very long view on India. We think very positively on the prospects," said David Redfern, chief strategic officer, GSK.

Publication: The Hindu Business Line

Edition: National (*Opinion*)

Date: December 18, 2013

Headline: [The MNC thumbs up](#)

Synopsis: India needs not only GSK, Unilever and PepsiCo, but also the likes of Posco, Shell and BHP Billiton. Whether or not Moody's and Standard & Poor's (S&P) are going to downgrade India's credit rating, one thing is clear: multinationals are increasingly bullish about the country's long-term growth potential. The latest proof of this is GlaxoSmithKline plc's (GSK) decision to raise the stake in its listed Indian pharma subsidiary from 50.7 to 75 per cent. The British MNC is prepared to pay a 26 per cent premium over Friday's closing share price to acquire the additional holding in GSK Pharmaceuticals Ltd at a cost of Rs 6,389 crore or over \$1 billion. This, despite recent setbacks in India – the patent on the company's breast cancer drug, Tykerb, was revoked, and its flagship antibiotic brand, Augmentin was placed under price control.

Publication: The Indian Express

Edition: Mumbai

Journalist: Tabassum Barnagarwala

Date: December 18, 2013

Headline: [TMH, NGOs locate unused buildings to house cancer patients' relatives](#)

Synopsis: In a move that will benefit economically-backward cancer patients, the Parel-based Tata Memorial Hospital (TMH) recently identified three unused buildings at a hospital in Wadala to provide accommodation to patients' families. In addition, some space will also be allotted in a six-storey structure to be constructed on Haffkine Institute's plot near TMH. TMH — a cancer treatment and research centre receives around 1,000 cancer patients for treatment every day. "Almost 80 per cent patients come from outside Mumbai for treatment. Several families come with a few thousand rupees and find it difficult to spend a huge amount on just accommodation. So, they prefer sleeping on roads," said Shalini Jatia, a social worker with the hospital's paediatric oncology department.

Publication: Pharmambiz

Edition: Mumbai

Date: December 18, 2013

Headline: [Tata Memorial Hospital to organise 3-day CAN-INDIA Conclave 2013 in Mumbai from Dec 19](#)

Synopsis: Tata Memorial Hospital, Mumbai is organising three-day the CAN-INDIA Conclave 2013, a first-of-its-kind annual scientific conference, for cancer NGOs (non-governmental organisations) and support groups at the Hospital from December 19 to 21, 2013. The main aim is to bring all pharmaceutical companies, NGOs, stakeholders from all domain of cancer which includes: doctors, nurses, volunteers, cancer survivors and government under one roof. This Conclave will act as a platform to exchange ideas/ thoughts/ collaborate while maintaining their individual identity. It will also give an opportunity to interact with the international and local charitable organisations including governmental and non-governmental agencies and individuals interested or involved in the fight against cancer.

Innovation

Publication: Mint

Edition: National

Journalist: Vidya Krishnan

Date: December 18, 2013

Headline: [Locally developed thalassemia testing kits to reduce costs](#)

Synopsis: Diagnostic kit for a pair of blood disorders will be sold for Rs.400, against the Rs.15,000 price tag for kits developed by private firms. India on Tuesday launched a locally developed diagnostic kit for a pair of blood disorders that will be sold for Rs.400, compared with the Rs.15,000 price tag for kits developed by private companies.

Publication: Deccan Chronicle (Reproduced by ANI)(also appeared in the Hindustan Times: Print)

Edition: Online

Date: December 18th, 2013

Headline: [Scientists discover potential vaccine that could help eradicate malaria](#)

Synopsis: Researchers have discovered a key process during the invasion of the blood cell by the Malaria parasite, and have found a way to block this invasion. With this new knowledge, the scientists from Singapore's Nanyang Technological University (NTU) are looking to collaborate with the industry on a vaccine against Malaria which can be developed within the next five years if accelerated by vaccine development companies.