



News Updates: December 24, 2013

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

Publication: The Economic Times (Opinion)

Edition: National

Date: December 24, 2013

Author: D G Shah, Secretary general, Indian Pharmaceutical Alliance

Headline: [The full spectrum on FDI in brownfield companies](#)

Synopsis: Acquisition of brownfield, or existing, pharmaceutical companies may be seen in different perspectives as greenfield, or new, projects are permitted 100% equity via the automatic route. India has sought FDI mainly to bridge the shortfall in investment or to facilitate the flow of know-how and technology. We must first assess the need of the pharma sector and then evaluate whether mere change of ownership would meet its needs.

Patents/ Intellectual Property Rights/ Compulsory Drug Licensing

Publication: Business Standard

Edition: National

Date: December 23

Headline: [Biocon's oral insulin project expected to be delayed further](#)

Synopsis: One of the most ambitious projects of Biocon - the development of oral insulin - is expected to be delayed further. The Bangalore-based company which is attempting to develop this drug for the past few years - first on its own and for the past one year with global pharmaceutical major Bristol Myers Squibb (BMS), is expected to pick up talks with BMS on the future of the project going further. This move may be precipitated by the last week's decision by BMS to exit a joint venture for diabetes with Astra Zeneca for close to \$4.3 billion. Upon completion of the transaction, AstraZeneca will own intellectual property and global rights for the development, manufacture and commercialisation of the diabetes business, which includes Onglyza (saxagliptin), Kombiglyze XR (saxagliptin and metformin HCl extended release), Komboglyze (saxagliptin and metformin HCl), dapagliflozin (marketed as Forxiga outside the US), Byetta (exenatide), Bydureon (exenatide extended-release for injectable suspension), metreleptin and Symlin (pramlintide acetate).

Drug Pricing

Publication: Daily News and Analysis

Edition: Mumbai

Date: December 23

Headline: [Maharashtra whips overselling chemists](#)

Synopsis: When 24-year-old Pradnya Gaikwad was prescribed two doses of a medicine over two days, she sought to buy four pills; but she ended up buying an entire strip of 12 expensive pills. For, the chemist concerned refused to sell the medicine as prescribed. "The chemist said he can't retain half the packet," said Gaikwad. Such forced sale of excessive medicine is against the Maharashtra state government regulations which state that chemists need to sell even one tablet, if required. "No chemist can refuse to dispense what a patient seeks," said Mahesh Zagade, commissioner of the Maharashtra Food & Drug Administration (MFDA). Typically, doctors prescribe small doses of medicine to observe their impact. Gaikwad's prescription was changed after two days. By then, it was too late to return the unused pills to the chemist.

OPPI

Publication: Business Standard

Edition: Online (Reproduced from IANS)

Date: December 23, 2013

Headline: [India working towards eliminating tropical diseases: Official](#)

Report:

The Indian government is working with all stakeholders as well as the community towards controlling and eliminating 17 identified Neglected Tropical Diseases (NTD) such as rabies, leprosy and Japanese encephalitis, a health ministry official said Monday. NTDs are a group of tropical infections which are especially endemic in low-income populations in developing regions of Africa, Asia and the Americas.

“India has supported the London Declaration of 2012 and has joined other member nations at the World Health Assembly this year to adopt a resolution for controlling, eliminating and eradicating 17 identified NTDs. The Indian government is working with all stakeholders and the community towards meeting these objectives,” said Anshu Prakash, joint secretary in the health ministry.

Organisation of Pharmaceutical Producers of India (OPPI) director general Ranjana Smetacek said: “For India to achieve its ambitious NTD goals, we must work with other sectors to ensure communities have access to clean water, sanitation, improved living conditions, vector control and stronger health systems in endemic areas.”

The need to eliminate and control the NTDs was discussed during a meeting of experts from Global Health Progress, OPPI, and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), a release said here. Globally, NTDs affect over one billion people, are more prevalent in rural areas and predominantly affect the poorest and most marginalized communities. With 58 percent of leprosy cases, 40 percent of lymphatic filariasis and 34 percent of all dengue cases, India shoulders a high burden of several NTDs.

Also appeared in

Firstpost: [India working towards eliminating tropical diseases: Official](#)

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

Publication: The Financial Express

Edition: National (*Opinion*)

Date: December 24

Headline: [Royal fuss](#)

Synopsis: Commerce and industry minister Anand Sharma is right when he points to a doubling of royalty payments from India as a proportion of inwards FDI over the years, but he needs to put it in perspective; more important, writing to the finance ministry to find some way to address the issue only lends credence to the view that his ministry is increasingly looking protectionist. So, it was the commerce ministry that was against the Mylan \$1.8 billion acquisition of Strides Arcolabs' Agila Specialties on grounds that Indian pharma units were being gobbled up by MNCs—it even put out a Cabinet note on restricting FDI acquisitions in pharma—and the ministry dragged its feet on the FDI in multi-brand retail fine print for so long, global retailers almost gave up on India. In the case of royalty payments also, a favourite issue of investor advisory firms, there is the issue of the data that can be looked at differently, and there is the question of the mindset. Outflows on royalty and technical fees, broadly classified as ‘intellectual property charges’ in RBI data have risen from \$2 billion in FY10 to \$4.2 billion in FY13—this works out to a rise from 7.9% of FDI inflows to 19.1%; for the first half of FY14, the proportion is 15.1%. But once you add the reinvested earnings of foreign firms—and that is the globally accepted standard to calculate FDI—the numbers fall, to 5.3% in FY10 and 10.2% in the first half of FY14.

Publication: Business Standard

Edition: National

Journalist: Sohini Das

Date: December 24, 2013

Headline: [With Elder, Torrent springs out of price bind](#)

Synopsis: Torrent Pharmaceuticals' Rs 2,004-crore acquisition of Elder Pharma's 30 brands will result in momentous changes for both companies. Elder will lose the cream of its business. Analysts expect it to henceforth focus on its business abroad. For Torrent, which draws a large chunk of its revenues from overseas,

the acquisition will increase its share of the domestic market and expand its presence to newer therapeutic segments. Torrent's current market share is 2 per cent and it is placed 17th on the pecking order - the acquisition will raise it to 2.7 per cent and improve its rank to 12th. The gains in some key segments will be more dramatic: from 0.4 per cent to 6.2 per cent in vitamins, minerals and nutrients, and women's healthcare (rank will jump from 45th to 3rd), and from 0.9 per cent to 2.7 per cent in pain management (rank to improve from 27th to 11th).

Publication: Financial Express

Edition: National

Date: December 24, 2013

Headline: [Torrent Pharma seeks nod for 5k-cr borrowing limit](#)

Synopsis: Torrent Pharmaceuticals has sought shareholder nod for enhancing its borrowing limit to R5,000 crore from R3,000 crore. "Considering the company's future growth plans, both organic and inorganic, including the proposed acquisition of identified Indian branded formulation business of Elder Pharmaceuticals, it is proposed to raise the above borrowing limits," the company said.

Publication: Financial Express

Edition: National

Date: December 24, 2013

Headline: [Sun Pharma stock presents opportunity: Morgan Stanley](#)

Synopsis: \$-600-million market cap de-merged from Sun, got a complete FDA response letter on its second drug in the NDDS pipeline, Venlafaxine 300mg.

The USFDA did not approve the drug. In May, FDA did not approve SPARC's first product, levetiracetam XR 1000/1500 mg. (SPARC plans to submit additional studies for the drug). In its response, the FDA requested additional studies related to efficacy and safety. According to the company, these studies may relate to head-to-head comparisons with the innovator's product. In view of the additional cost and time required to perform these studies and obtain product approval, SPARC is evaluating Venla's commercial viability. We had estimated \$30 million in sales potential from Venla in F2015 (with some upside share with Sun) and believed that this was a rather small opportunity for Sun/SPARC. In all, SPARC is developing more than a dozen new drug delivery system (NDDS) drugs. Sun is likely to share some value in SPARC's pipeline through manufacturing and marketing partnerships. We expect this to be a mid- to longer-term growth driver for Sun. We reiterate our 'overweight' rating on Sun and view the current stock weakness as a good opportunity to buy the stock.

Clinical Trials

Publication: Pharmabiz

Edition: Online

Date: December 24, 2013

Headline: [Kerala govt issues order to carry out clinical study for proprietary and patented Ayurveda products](#)

Synopsis: The government of Kerala has accorded sanction to carry out clinical study and safety study for proprietary and patented Ayurveda products before grant of license in order to prove their efficacy and safety before hitting the market. To conduct the human trials, government has identified and designated three Ayurveda colleges from government and semi government sectors. The colleges and the department of Ayurveda are now engaged in forming a state level monitoring committee in order to associate with the ethical committees of the concerned colleges for the smooth conduct of the trials.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Economic Times

Edition: National

Journalist: Dhirendra Kumar (by-lined)

Date: December 24, 2013

Headline: [Premium is a Wrong Metric to Measure Insurers' Health](#)

Synopsis: Over the last few days, an advertisement placed by a body called 'Global Federation of Insurance Associations' has appeared in a number of publications. This advertisement is written in the form of an open letter to the Prime Minister, with copy to the finance, commerce and parliamentary affairs ministers. The letter is essentially an exhortation to get the amended insurance bill passed and talks almost entirely about the FDI that passing this bill will bring about and the signal it will send about India being 'open for business'. That's all well and good, and there's also one bit about the insurance industries' customers, which goes "While the Indian market has witnessed tremendous growth, there remain high levels of underinsurance. The security a family or business achieves by insuring its most valuable assets helps supplement programmes already in place by the government to lift the living standards of the Indian people." That's a noble thought indeed and is expressed in a manner that appears to be designed to push all the right buttons — get FDI and make Indians secure. However, the basic premise here is that the insurance industry is in the business of providing insurance cover and the coming of foreign insurance companies has enhanced this activity. Is this premise correct? The unfortunate answer to that question is that no one seems to know, neither the Irda, nor the government. The sad part is that not only do they not know, they seem not to care that this measure is important.

Drug Pricing / Price Control

Publication: Business Standard

Edition: National

Journalist: Sushmi Dey

Date: December 24, 2013

Headline: [Pharma firms might resume sales of analgin-based drugs](#)

Synopsis: Soon, drug makers might be able to resume the sale of analgin, the popular pain-relief drug. The Drugs Controller General of India is considering the recommendations of its advisory body to revoke the suspension of the sale of analgin-based medicines in the country. Various pharmaceutical companies, including Sanofi and Sun Pharma, which own analgin-based brands such as Novalgin, Baralgin and Metnimez, are likely to gain from such a move. For short duration: The Drug Technical Advisory Board, which discussed the ban on the sale of analgin at a recent meeting, said the duration of analgin treatment was only a few days and, therefore, the use of the drug might be continued according to the approved indication. The board's suggestions have been submitted to the drug regulator and the health ministry, which will take a final decision on the matter.

Publication: The Economic Times

Edition: National

Journalist: Soma Das

Date: December 24, 2013

Headline: [Government may have to reset prices of essential drugs](#)

Synopsis: Seven months into the new pharma pricing regime, the government may have to go back to the drawing board and reset prices of essential drugs, adding to the prevailing confusion in the domestic drug market. Also, it may now have to set free time-release drugs from regulation, which means that these new generation drugs will remain expensive. This class of drugs release medicine at a measured pace to improve efficacy and compliance of patients and involves different forms of releases: modified, sustained, extended, controlled and delayed release therapies.

General Industry

Publication: Business Standard

Edition: Chandigarh

Date: December 24, 2013

Headline: [From chartered accountant to drug manufacturer](#)

Synopsis: In the late 1980s, when the Indian economy had yet to open its doors to foreign direct investment in the pharmaceuticals sector, and few indigenous drug manufacturers understood the significance of intellectual

property, a young chartered accountant decided to try his luck in the industry's bulk drugs segment. It was while auditing a pharma company in 1988 that Pawan Chaudhary, a novice chartered accountant then aged 25, decided to start his own venture. A first-generation entrepreneur, Chaudhary secured funds from his family as well as from banks to set up Venus Glucose Private Limited at Panchkula, in Haryana.

Publication: The Hindu Business Line

Edition: Online

Date: December 24, 2013

Headline: [Eisai Pharma gets award for CSR activity](#)

Synopsis: Eisai Pharma Pvt Ltd, the Indian subsidiary of Tokyo-based Eisai Co Ltd, has been declared winner for the corporate social responsibility activities by UBM India, according to a press release. The UBM India awards have been instituted to honour companies who have excelled in pharmaceuticals and who contribute to the growth and development of the Indian industry and also the economy. The awards celebrated thinkers and creators breaking new ground in formulation, process development and packaging.

Publication: The Times of India

Edition: Online

Date: December 24, 2013

Headline: ['Tackle corruption first to address medical negligence'](#)

Synopsis: Medical negligence in India can only be tackled when corruption and incompetence in healthcare is addressed, said Dr Kunal Saha who was awarded the highest-ever amount as compensation for medical negligence in the country this October. "The number of doctors penalized for medical negligence is statistically nil in India. We know that doctors are not perfect," he quipped here on Monday. Saha, along with judicial experts, spoke on medical negligence in the context of the recent Supreme Court verdict awarding him Rs 11 crore as compensation after the death of his wife, Anuradha, at a Kolkata hospital in 1998. Highlighting various aspects of the judgment, Saha said the ruling would not set a precedent for other courts to follow.

Publication: The Times of India

Edition: Online

Date: December 24, 2013

Headline: [Chennai witnesses spike in typhoid cases](#)

Synopsis: Water contamination in several areas of the city has resulted in doctors, particularly paediatricians, seeing a spike in the number of typhoid cases in the past few weeks. Doctors, however, say very few cases require admission and IV fluids for dehydration. A majority show mild infection and are treatable with medication. General Physician Dr C Bharaneedharan of Global Health City, who has been treating at least three cases of typhoid everyday, says rampant water contamination in a few areas is the main cause for the rise in typhoid cases. People contract typhoid when they ingest food, water and other liquids infected by salmonella typhi, a disease-causing bacteria that spreads through the feces of an infected person.

Publication: The Hindu

Edition: Delhi

Journalist: Sarabjit Pandher

Date: December 24, 2013

Headline: [One more hospital to join Punjab's war on cancer](#)

Synopsis: Punjab's war on cancer will receive a fillip when Prime Minister Manmohan Singh lays the foundation stone for a super specialty treatment and research centre at Mullanpur town on the outskirts of Chandigarh on December 30. The Rs. 450-crore state-of-the-art facility is being established by the Bhaba Atomic Research Centre on the lines of the Tata Memorial Hospital, Mumbai. Chief Minister Parkash Singh Badal, who is a cancer survivor, is personally leading the campaign against the disease. His wife succumbed to it. On Monday, he gave consent for starting the scheme of providing cashless treatment to patients at one-and-half dozen empanelled

hospitals from January. Treatment will be financed from the Chief Minister's Cancer Relief Fund. Under the scheme, patients need not obtain prior sanction for availing themselves of the facilities there. According to Health Secretary Vinni Mahajan, a government census revealed that cancer caused 34,430 deaths in recent years and another 24,659 persons were still afflicted. Apart from empanelling hospitals for subsidised treatment, the government has come up with the Cancer and Drug Addiction Treatment Infrastructure Act 2013 and raised a corpus of about Rs. 250 crore from various activities in the public sector and set up specialised facilities for treatment.

Publication: Pharmabiz

Edition: Online

Date: December 24, 2013

Headline: [WHO's Uppsala Monitoring Centre looks to make India as hub for pharmacovigilance training](#)

Synopsis: The World Health Organisation's Uppsala Monitoring Centre is now looking to make India as a hub for pharmacovigilance training. The Organisation recognised India's concerted efforts in the area of pharmacovigilance but observed that the country needed to play a bigger role in the global landscape of adverse drug reaction (ADR) monitoring. "India should be made as hub for pharmacovigilance training. The country needs to sustain the pace of patient safety and improve the drug reaction reporting culture in India among doctors. It will need to also adopt VigiLyze to have a global view of ADR and adopt the VigiMed communication platform to enable easy access to safety concerns in other countries besides check regulatory status and expedite sharing of drug information," said Sten Olsson, WHO Programme Expert and head of the Global Outreach Department at the Uppsala Monitoring Centre.

Publication: Mint (Reproduced from The Wall Street Journal)

Edition: National

Journalist: Serena Ng

Date: December 24, 2013

Headline: [Marketers track flu outbreaks closely](#)

Synopsis: This winter when you get flu shots, research symptoms online or complain about coughs and body aches on [Twitter](#), consumer-products makers will be watching. The flu is a big moneymaker for companies that produce tissues, disinfecting wipes and cold remedies, and they are finding new ways to predict and chase outbreaks around the country to make the most of the opportunity. The key is having commercials and other ads on hand, ready to roll out in markets where the flu is just starting to pick up. Show up too early, and people don't feel the impulse to buy. Show up too late, and sufferers will have already loaded up on rivals' offerings. "We want to market more when people are getting sick, and not when people are well," said Ted Karkus, chief executive of [ProPhase Labs Inc.](#), [PRPH -2.42%](#) which makes and sells Cold-EEZE lozenges and other over-the-counter cold remedies.

Publication: The Tribune

Edition: National

Date: December 24, 2013

Headline: [Maharashtra begins rolling out free drugs in hospitals](#)

Synopsis: Borrowing a leaf from the pages of the former Congress government in Rajasthan, the Maharashtra Government has begun a project to provide free drugs to patients in government hospitals. Under the project, several important drugs will be provided free of cost to patients irrespective of their economic status. "We have a list of 422 essential drugs which will be prescribed to patients who need them," says Radhakrishna Pawar, Assistant Director, Directorate of Health Services. State-run hospitals including primary health centres will be required to install the e-Aushadhi software which will enable them to update the stock position at their pharmacies in real time, according to Pawar. The medicines would then be distributed to the hospitals as per their requirements. The DHS has already sent a list of essential medicines required for the project to the state government. Tenders would be issued and pharmaceutical companies will be required to send in their bids. Only generic drugs will be issued under this scheme, according to Pawar.

Publication: The Asian Age
Edition: National
Date: December 24, 2013
Headline: [Heart news on Polio](#) (opinion)

Synopsis: India is just weeks from getting a WHO certificate that it is free of polio. A near impossible task, which was made even more challenging by the invariably self-defeating numbers India has to contend with on any health issue, has been tackled in the last four years with an evangelical zeal involving the reaching of polio drops to 170 million children through two million vaccinators. More than `15,000 crore has been spent since 2009 when the country was said to have had more cases of polio than any other country. The task ahead is even more challenging as all laboratory sources of wild polio virus have to be destroyed or stored under the most stringent parameters of bio-safety. But then again, that would only be half the task completed since to keep the country free of the debilitating disease, which blights the lives of so many soon after birth, scarring them forever, is not going to be easy given the endemic zone of Pakistan and Afghanistan is not far away and the Syrian civil war is said to have facilitated a fearsome outbreak. While WHO, Unicef, Rotary International and the Bill & Melinda Gates Foundation have lent their shoulders to the wheel in a most committed way, keeping polio out is only a part of what India has to achieve to secure the lives of all its newborn children. A Unicef report says 14 lakh children under the age of five died in 2012 from preventable diseases like pneumonia and diarrhoea, not to speak of malnutrition, which is allied to poverty and ignorance.

Innovation

Publication: The Hindu
Edition: National
Journalist: Aarti Dhar
Date: December 24, 2013
Headline: [Indigenous device detecting early cervical cancer launched](#)

Synopsis: Magnivisualizer is a user-friendly device costing about Rs. 10,000. The Union Health and Family Welfare Ministry on Monday launched indigenous equipment that can detect early cervical cancer and be used even by healthcare workers with basic training. The device AV Magnivisualizer which was developed by the Institute of Cytology and Preventive Oncology under the Indian Council of Medical Research (ICMR) has 95 per cent accuracy for detecting pre-cancerous lesions. Randomised clinical control trials have confirmed its efficacy in reducing incidence and mortality of the disease. It can be made available in remote rural areas.

Also appeared in The Asian Age (no link available)

The Economic Times online - [India launches its indigenous cervical cancer screening device](#)
Press Information Bureau - [Shri Ghulam Nabi Azad Launches 'AV Magni-Visualiser' Screening Device for Cervical Cancer](#)

Publication: The Hindu Business Line
Edition: Online
Date: December 23, 2013
Headline: [Frugal innovations to keep India healthy](#)

Synopsis: From a smart medicine pack that keeps a tab on a person taking tuberculosis medicines to technology that identifies the right blood vessel for an intra-venous procedure, innovations are now coming in small packages. And research competitions are challenging these "Edisons of tomorrow" — students, scientists and entrepreneurs — by encouraging them to think-up novel solutions in healthcare. Prototype development: Take the 'Grand Challenges in Tuberculosis Control' programme for instance. Winners get \$30,000 as a grant for six months to develop a prototype. And those who scale this challenge get \$100,000 each to integrate the innovation into India's healthcare system. The TB-control challenge, an initiative from IKP Knowledge Park, has the US Agency for International Development and the Bill and Melinda Gates Foundation, as partners. Big innovations are required and will continue, but the idea here is to open opportunities for effective, high-volume and low-cost solutions, says Gopichand Katragadda, Chairman and Managing Director of GE India Technology

Centre (GE-ITC). GE's Edison Challenge gives the winner a Rs 10-lakh grant, and the runner-up, Rs 5 lakh.

Publication: The Financial Express
Edition: Online (Reproduced from PTI)
Date: December 24, 2013
Headline: [New finding could lead to better malaria treatments](#)

Synopsis: Scientists have identified a new method to stop malaria parasites from multiplying, paving way for new treatments for the deadly mosquito-borne disease. Researchers found that blocking the activity of an enzyme called NMT in the most common malaria parasite prevents mice from showing symptoms and extends their lifespan. The team are working to design molecules that target NMT more potently, and hope to start clinical trials of potential treatments within four years. Although a variety of antimalarial drugs are available, some strains of the parasite are resistant to treatment. These strains are becoming more common, with treatment failures reported across multiple frontline drugs. If acute illness is cured, the parasite can remain dormant in the blood and return to cause illness later. Malaria vaccines have been researched intensively, but none have been introduced into clinical practice.

Publication: The Times of India
Edition: Varanasi
Date: December 24, 2013
Headline: [Efforts on for ayurvedic cure of Alzheimer's](#)

Synopsis: In a major achievement in the field of medicine, Banaras Hindu University (BHU) is making all efforts to introduce medicines for Alzheimer's and Parkinson's diseases soon. Prof GP Dubey of the Institute of Medical Sciences (IMS), BHU has claimed to have received global patent for the plant based products prepared from three medicinal plants. These plants have been found useful in prevention and management of not only Alzheimer's and Parkinson's disease but also in various age related neurogenerative changes. These plants are Bacopa Monnieri (Brahmi), Hippophae rhamnoides (Amlavetus) and Dioscorea bulbifera (Varahikand).

Publication: The Times of India (also appeared in Mint)
Edition: National
Date: December 24, 2013
Headline: [Malaria parasite's growth can be halted](#)

Synopsis: Scientists have identified a new method to stop malaria parasites from multiplying, paving way for new treatments for the deadly mosquito-borne disease. Researchers found that blocking the activity of an enzyme called NMT in the most common malaria parasite prevents mice from showing symptoms and extends their lifespan. The team is working to design molecules that target NMT more potently, and hope to start clinical trials of potential treatments within four years. Although a variety of antimalarial drugs are available, some strains of the parasite are resistant to treatment. These strains are becoming more common. The new study shows that NMT is involved in a wide range of essential processes in the parasite cell. The experts have tested a handful of molecules that block the activity of NMT in the parasite living inside human red blood cells.

Publication: Financial Chronicle
Edition: National
Date: December 24, 2013
Headline: [The peptide revolution](#)

Synopsis: More and more medical researchers look to peptides for answers, seeking cures for everything from common illnesses to complex diseases. The word, peptide, originates from 'peptein,' the Greek word for 'pepsis,' or 'to digest.' It was first coined by Hermann Emil Louis Fischer, a German chemist and Nobel laureate, at the beginning of the last century, evidencing that peptides are characteristically generated by our gut. Peptides are, in reality, more than

representative of our digestive process or natural biological bustle — they are, in essence, our molecules of emotions, the emblematic icons of our feelings. They are found in all living organisms; they perform a pivotal role in every form of biological activity.