**News Updates: December 31, 2013**

**OPPI**

**Publication: The Economic Times**
**Edition: National** *(Editorial)*
**Author: Ranjana Smetacek**
**Date: December 31, 2013**
**Headline:** **Will India achieve pharma vision 2020?**

**Article:**
The government is committed to making India one of the world's leading destinations for end-to-end drug discovery and innovation by 2020. Although India has achieved the distinction of being the world's No. 1 supplier of low-cost generic medicines, in recent years, a toxic brew of misguided government policy and shortsighted business practices has crippled our efforts to become a drug discovery and innovation powerhouse, even while jeopardising our access to foreign markets due to quality issues .

2013 has been a year with mixed blessings and some policy decisions taken this year are likely to have farreaching impact on the future of the pharmaceutical industry in India. In March this year, the Intellectual Property Appellate Board upheld the compulsory licence (CL) issued for the manufacture and sale of a generic version of Bayer's Nexavar in India citing affordability and product access as the reasons for the decision. While the grant of a CL is justified in a national emergency, broadening the scope to affordability can result in abuse of this provision and be counterproductive to pharmaceutical innovation in India. CL must remain the exception rather than the rule.

On the upside, after much deliberation, the government ruled in favour of 100% foreign direct investment in the pharmaceutical industry. This is a positive move and will allow India to invest in R&D, enhance local capabilities and find solutions to endemic health problems. 2013 also saw the success of several public-private partnerships between government and MNCs in the pharmaceutical industry.

Such partnerships hold great potential when it comes to larger healthcare access in India.

However, the crisis in the clinical research industry that peaked this year needs to be resolved without delay. India has the potential to become a global hub for clinical trials and banning trials for new chemical entities, unless vetted by the Union health secretary, is not the answer. To grow, both in terms of value and volume, India needs to strengthen its commercial capabilities, realise its R&D prowess and collaborate with stakeholders within and outside the industry to drive access and shape the market.

Three years ago, the then-President Pratibha Patil declared this to be India's "Decade of Innovation". However, we have since lost sight of an important fact: promoting innovation means protecting our innovators and creators, attracting world-class R&D, and creating and sustaining high-quality future jobs through robust protection of intellectual property (IP) rights.

Today, India is primarily a branded generics supplier with limited focus on innovation and research. While we excel at developing copies of offpatent drugs, we lag far behind other member-countries of the World Trade Organization in new drug development.

India experienced a significant increase in the number of patents granted and in force immediately following the implementation of the TRIPS agreement in 2005, but since then, there has been a pronounced fall. This fall coincides with a wider weakening of India's IP environment and hurts domestic inventors as well as foreign companies.

This shows that while India is potentially well-placed to lead in R&D, it has in the past lacked the will to build

on this potential. India has some of the finest minds available for research. It has a well-developed pharmaceutical industry that can ably support R&D but for many complex reasons, this has not happened. The time to set things right is now and India is taking the right steps in this direction.

## Pharma Industry - 2013

**Publication: Financial Express**
**Edition: National**
**Date: December 31, 2013**
**Headline: The road was uneven for health in 2013**

*Scan of the report: (link not available)*

**Publication: Financial Chronicle**
**Edition: Mumbai**
**Date: December 31, 2013**
**Headline: Pharma industry looks to rebound in '14**

**Synopsis:** The Indian pharmaceutical business, which saw a sharp sales decline in August to October and a deceleration in the decline in November, is expected to grow at 9-10 per cent in 2013-14. In 2014-15 it will grow much faster at 12-14 per cent. The pharmaceutical market is worth Rs 77,000 crore a year. According to data of market research firm IMS Health, November saw growth of 13.8 per cent. The sector had seen single-digit growth in each of the three months of August to October. In September growth was at as low 1.8 per cent.

**Publication: Business Today**
**Edition: Online**
**Date: December 30, 2013**
**Headline: Niche drugs key to growth of pharma industry in 2014**

**Synopsis:** The Indian pharmaceutical industry faces a crucial new year. Until now, the local industry has largely followed a growth model that focused on launching cheap generic versions of branded innovator drugs made by global pharmaceutical companies. But, increasingly this is becoming an unviable model and companies may no longer be able to depend on this strategy, as most blockbuster drugs will be off-patent by 2015. Critical for survival in this era will be investment in what the pharmaceutical industry calls "limited competition drugs" and differentiated products. Limited competition drugs are generic drugs that are either difficult to make or are not made by many players. Differential products are existing molecules but drugs with different dosage or administration mechanism.

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

**Publication: Pharmabiz**
**Edition: Online**
**Date: December 31, 2013**
**Headline: India bio-pharma can bounce back in 2014 driven by biosimilar norms, low cost manufacture: Biocon Chief**

**Synopsis:** India's bio-pharma industry could see the year 2014 to bring in the much-needed positive change. The country's early adoption of biosimilar regulatory guidelines, accrued benefits of low cost manufacture and access to quality talent pool that could help the industry spring back, stated Kiran Mazumdar-Shaw, chairman and managing director, Biocon Limited. The industry had a tough 2013 driven by the Indian economy having to experience one of its most turbulent times. Indian bio-pharma sector decelerated to 5.2 per cent in 2013 from an average growth of 12 per cent the previous year. Adverse policy moves like the drug pricing, foreign direct investment (FDI), clinical trials and compulsory licensing made matters worse.

An overactive US FDA hauled up several leading Indian pharma companies for non-compliance. All these negative developments collectively turned 2013 into an 'Annus Horribilis' for the Indian bio-pharma sector, she added.

## Drug Pricing / Price Control

**Publication: The Hindu Business Line**
**Edition: National**
**Date: December 31, 2013**
**Headline: Govt okays drug price cap review by 5 firms**

**Scan of the report** *(link not available)*
Also appeared in DNA

## FDA / Drug Regulatory / DCGI / Pharma Policy

**Publication: Business Standard**
**Edition: National**
**Date: December 31, 2013**
**Headline: US FDA likely to inspect new Visakhapatnam facility of Divi's Labs in Jan**

**Synopsis:** The US drug regulator may inspect a new facility of Hyderabad-based Divi's Laboratories in January, sources said. The move assumes significance because a go-ahead from the US Food and Drug Administration (US FDA) for the new unit in Visakhapatnam is likely to give a huge boost to the company's revenues in upcoming quarters. An email questionnaire sent to Divi's Laboratories did not elicit any response. Shares of the company jumped around five per cent in the past one week to touch a high of Rs 1,235.50 on Monday from a low of Rs 1,171 last Thursday on the Bombay Stock Exchange. On Monday, Divi's Labs' shares closed at Rs 1219.05 apiece, down 0.27 per cent from the previous close.

**Publication: Pharmabiz**
**Edition: Online**
**Date: December 31, 2013**
**Headline: DCGI to conclude week long drive to check quality of medicines in Rajasthan**

**Synopsis:** A team of drug control officials from the Drug Controller General of India (DCGI) office along with the Rajasthan drug control officials have commenced random sampling of medicines distributed under Rajasthan Free Drug Distribution Scheme. The scheme started two years ago by the Rajasthan government. The sampling exercise started with Northern States like Jammu and Kashmir, Himachal Pradesh and Uttar Pradesh four months back and is now being done in Rajasthan and will be taken up in Maharashtra, Andhra Pradesh and Karnataka in the coming months. Says Dr G N Singh, DGCI, "The exercise of doing surveillance through random sampling in drug stores have now been started in Rajasthan with the aim of protecting patient's rights necessitated by the growing health safety awareness across the country. Every month a state will be chosen and will be put under surveillance to keep a check on the quality of medicines."

**Publication: The Times of India**
**Edition: Mumbai**
**Date: December 31, 2013**
**Headline: Govt makes notorious 'date rape' drug ketamine harder to buy or sell**

**Synopsis:** Anaesthetic drug ketamine, notorious for its use as a date rape drug, has finally been included in the stringent schedule X of the Drug and Cosmetics Act to curb its easy availability. Now, its buyers and sellers have to maintain extensive documentation and be ready for governmental checks. A hallucinogen, ketamine leaves the user with a sense of euphoria or "feeling of detachment," say experts. Available in liquid and powder form, its overuse is capable of numbing senses and playing havoc with the body's motor control. Doctors abroad have documented life-threatening conditions, such as cardiac arrest and paralysis,

occurring from its overuse. In India, though details of its abuse are scarce, de-addiction centres teeming with victims—mostly teenagers—indicate the problem is severe here too.

**Publication: Pharmabiz**
**Edition: Online**
**Date: December 31, 2013**
**Headline: Odisha govt asks health ministry to enhance funding to beef up pharmacovigilance programme**

**Synopsis:** The Odisha government has asked the union health ministry to increase the funding for pharmacovigilance activities in the state. The state government's demand to this effect was conveyed to Dr A K Panda, joint secretary, ministry of health and family welfare and Dr GN Singh, drug controller general of India (DCGI) and secretary-cum-scientific director, Indian Pharmacopoeia Commission (IPC), who were in Odisha recently on a two-day visit to the state to have a first-hand information about the adverse drug reaction (ADR) monitoring centres in the state.

**Publication: Pharmabiz**
**Edition: Online**
**Date: December 31, 2013**
**Headline: Sanofi's subsidiary Genzyme gets complete response letter for Lemtrada application from US FDA**

**Synopsis:** Sanofi recently announced that its subsidiary Genzyme has received a Complete Response Letter from the US Food and Drug Administration (FDA) for its supplemental Biologics License Application seeking approval of Lemtrada (alemtuzumab) for the treatment of relapsing forms of multiple sclerosis. A Complete Response Letter informs companies that an application is not ready for approval. FDA has taken the position that Genzyme has not submitted evidence from adequate and well-controlled studies that demonstrate the benefits of Lemtrada outweigh its serious adverse effects. Genzyme understands that the conclusion is related to the design of the completed phase III active comparator studies of Lemtrada in relapsing-remitting MS patients. FDA has also taken the position that one or more additional active comparator clinical trials of different design and execution are needed prior to the approval of Lemtrada.

Also appeared in Business Standard (Link not available)

**Publication: Mumbai Mirror**
**Edition: Mumbai**
**Date: December 31, 2013**
**Headline: Banned painkiller may make its way back to pharmacies for cancer patients**

**Synopsis:** Six months after the health ministry issued a ban on the addictive painkiller Dextropropoxyphene, the Drug Technical Advisory Board (DTAB) wants it revoked and has recommended that it be marketed only for cancer patients. Dextropropoxyphene and the other drugs that are part of its combination were banned on May 23 this year due to their addictive properties, which lead to bulk sales and severe health risks like hypotension, seizures and in extreme cases, death. The drug also landed in a controversy after one of the drugs that are part of its combination -- Spasmo Proxyvon -- manufactured by pharma major Wockhardt, was found to be sold in huge numbers despite the ban.

**Publication: The Telegraph (UK)**
**Edition: Online**
**Date: December 31, 2013**
**Headline: British regulator warns Indian drug companies after data scandal**

**Synopsis:** Indian manufacturers of cheap generic drugs prescribed by the National Health Service may not be trusted because several have altered the testing data submitted to Britain's regulator, according to the

agency's director of inspections. At least two Indian pharmaceutical firms which supply British chemists and hospitals had either failed to submit original data from tests on the drugs or actually changed the data on which the regulatory body decides whether to license the medicines for sale in Britain. The disclosure was made by Gerald Heddell, director of inspections at the Medicines and Healthcare Products Regulatory Agency which inspects all plants manufacturing drugs for use in Britain, in an interview with the Economic Times of India.

## General Industry

**Publication: MINT**
**Edition: National** *(Editorial)*
**Author: K. Srinath Reddy**
**Date: December 31, 2013**
**Headline: 2014: A political consensus on health?**

**Synopsis:** As Indians of all political persuasions brace themselves for a year of high drama where a fractious national campaign could end in an uncertain verdict and unforeseen coalitions, what will the future content and course of our health policy be? Will 2014 emerge as a year when health finally gets prioritized on the national development agenda, or will it get sidelined in the dust and din of politics as usual? As is widely discussed in public health forums, but seldom acknowledged in political debate, India's major health indicators fare poorly in comparison with our neighbours and economic peers. Our infant and maternal mortality rates are far higher than Sri Lanka's and we are worse off than Bangladesh and Nepal in current rates and the recent speed of decline. Our child malnutrition and immunization rates are worse than those of many countries in sub-Saharan Africa. Even as we worry about our diminishing demographic dividend because of child mortality and malnutrition, we lose more potentially productive years of life due to mid-life cardiovascular deaths in the age group of 35-64 years than China, the US and Russia combined.

**Publication: Business Standard**
**Edition: National** *(Editorial)*
**Date: December 31, 2013**
**Headline: Maternal mortality rate falls**

**Synopsis:** Maternal mortality, which remains high in India, indicating the country's deficit in human development, has nevertheless been steadily going down. The latest official figures, which measure the number of maternal deaths per 100,000 live births for the period 2010-12, indicate that maternal deaths in childbirth have fallen by more than half (55 per cent) over one and a half decades (1997-2012). The rate of decline over three three-year periods (covering 2003-2012) has been 14-17 per cent. But within this overall picture, the numbers offer an insight into the composition of the change. The decline is being achieved in good part by rapid progress by the most backward states. Thus, the difference between the best and the worst is narrowing. The difference between the best and the worst has fallen from 336 deaths in 1997-98 to 152 in 2010-12. Taking states individually, the difference between the worst (the highest in deaths), Assam, and the best (the lowest), Kerala, fell from 309 in 2007-09 to 262 in 2010-12.

**Publication: The Times of India**
**Edition: New Delhi**
**Date: December 31, 2013**
**Headline: Bitter cold puts elderly at risk**

**Synopsis:** Doctors say hypothermia, a fatal condition in which the body's temperature falls to abnormally low levels, is also common in extreme cold conditions. "Early morning walks should be postponed by two hours till the temperature gets warmer. Old people have weak lungs and many suffer from asthma and chronic bronchitis. Such patients should not be allowed to go out in foggy weather," said Dr A B Dey, head of geriatric unit at AIIMS. He said that family members should ensure elders are adequately dressed for cold- heads should be covered and socks are a must.

**Publication: Financial Chronicle**
**Edition: National**
**Date: December 31, 2013**
**Headline: Silent killer**

**Synopsis:** For a diabetic, the focus is invariably on the highs and lows of blood sugar levels, but close attention should be paid to heart and blood vessels, which otherwise could be doubly deadly. Very often we meet people suffering from diabetes and externally they look perfectly normal. There are no signs or symptoms that tell you that the person is suffering, but internally the disease is slowly eating them. The liver, kidneys, eyes and — most importantly — the heart bear the brunt of this disease.
The WHO estimates that India will have the dubious distinction of leading the world in diabetes. According to my estimate, we have already secured the top position as far as low awareness and ignorance of diabetes is concerned. For a diabetic, the focus is invariably on the highs and lows of blood sugar level. But besides blood sugar, close attention has to be paid to the heart and blood vessels.

**Publication: The Tribune**
**Edition: New Delhi**
**Date: December 31, 2013**
**Headline: Health scheme for children now in entire state** (No link available)

## Access, Affordability, Innovation

**Publication: The Economic Times**
**Edition: National**
**Date: December 31, 2013**
**Headline: 12 Technologies that can be game changers in 2014**

**Synopsis:** Life Sciences and healthcare: Wearable Devices Personal health monitoring is growing in developed markets and even in India, as people monitor their sleep, exercise impact, heart health, progress of pregnancy...The next year will make a significant advance as these devices begin to be connected to hospitals. A wearable devices network can be considered an Internet of Things, and will be influenced by SMAC, and is thus a good illustration of how cutting-edge technologies enforce each other. Wearable devices are not just for health monitoring.

**Publication: MINT**
**Edition: National**
**Date: December 31, 2013**
**Headline: Science and tech in 2014: The cutting edge**

**Synopsis:** 2013 was an exciting year for science and technology. Wearable technology and the quantified self: Clicking pictures with the wink of an eye, sending live feeds of surgeries, and watches that are phones are likely to become common next year. Genomics for rare diseases: The US this year funded a $25 million five-year research programme to explore the potential advantages and ethical challenges of sequencing every newborn's genome, while the UK saw the launch of a personal genome project that seeks 100,000 volunteers, who are asked to give open access to their genetic and health information.

**Publication: MINT**
**Edition: National**
**Date: December 31, 2013**
**Headline: Raising a genuine toast to your health and wealth**

**Synopsis:** If it is soaring medical bills that have made health insurance popular, reforms in the sector in 2013 will ensure that you are able to place more faith in them. Insurance Regulatory and Development Authority (Irda) rolled out two key pieces of regulation that not only make these policies better in terms of benefits but also improve the customer's understanding of the policy and processes by standardizing key health insurance terms and claims processes.

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**Publication: Deccan Herald**
**Edition: National**
**Date: December 31, 2013**
**Headline: Battling drug majors to offer affordable cancer cure**

**Synopsis:** The drug, Herceptin, is one of the most effective treatments for an aggressive form of breast cancer. But in India, at a cost of at least $18,000 for one course of treatment, only a small fraction of the women who need it get it. The Indian government last year threatened to allow production of less costly, generic versions of Herceptin. Its maker, Roche Holdings of Switzerland, initially resisted, but surrendered its patent rights this year in large measure because it concluded that it would lose a legal contest in Indian courts.

Also appeared in Mint: **The cancer divide**

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**Publication: Deccan Herald**
**Edition: National**
**Date: December 31, 2013**
**Headline: TB drug discovery held up for lack of funds**

**Synopsis:** An innovative Indian tuberculosis (TB) drug discovery programme has been held up for want of money on the eve of the clinical trial of a new medicine against drug-resistant TB. Research has been at a standstill since September in the Council of Scientific and Industrial Research's open source drug discovery (OSDD) programme which allows every willing scientist to chip in with their contribution in developing a new medicine against TB, a disease that kills lakhs every year in the country.

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**Publication: The Telegraph**
**Edition: New Delhi**
**Journalist: Sharmistha Das**
**Date: December 30, 2013**
**Headline: Right in the heart**

**Synopsis:** Rajesh Agarwal (name changed), a 42-year-old businessman from Calcutta, recently started noticing that he could not walk for even five minutes without becoming very short of breath. While he was a diabetic, Agarwal had no history of cardiac disease. An angiogram also revealed no signs of blockage. After several tests, he was diagnosed with severe diabetic cardiomyopathy. He was put on maximum possible medication and told to keep activity to a minimum for the moment. The only long-term solution was an artificial heart implant. And if things go right, he would become the first patient in Calcutta to undergo this operation. "If everything goes right we will operate by the end of January next year," says Dr Kunal Sarkar, senior vice-chairman, Medica Superspeciality Hospital, Calcutta. A team of 15 doctors, led by Dr Sarkar, will perform the procedure.

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**Publication: The Statesman** *(Reproduced by The Press Trust of India)*
**Edition: New Delhi**
**Date: December 31, 2013**
**Headline: Centre's move to fight cancer**

**Synopsis:** Expressing concern over increase in cases of cancer, Prime Minister Manmohan Singh today said here the UPA government is setting up a 'National Cancer Centre' to fight the dreaded disease. In his brief

address in Punjabi, the Prime Minister said that the National Cancer Centre will be linked with zonal and regional cancer centres. He was addressing a gathering after laying the foundation stone of Rs 450 crore Homi Bhabha Cancer Hospital and Research Centre here on the outskirts of Chandigarh in Mohali district of Punjab. The Mullanpur cancer hospital would be developed and established by Bhabha Atomic Research Centre (BARC) on the lines of Tata Memorial Hospital, Mumbai at a cost of Rs 450 crore, with Prime Minister expressing hope that the project would be completed within next four years.