



News Updates: November 30 – December 2, 2013

FDI

Publication: The Economic Times

Edition: National

Date: November 30, 2013

Headline: [Union Cabinet rejects DIPP proposal to limit FDI in pharma](#)

Synopsis: The Union Cabinet has rejected a proposal to limit foreign direct investment in domestic manufacturers of "rare and critical" drugs, a move that should boost sentiment and come as a relief to overseas companies looking to acquire Indian pharmaceutical companies. However, it said FDI deals in the pharma sector will not have a non-compete clause, giving existing promoters leeway to foray into the same line of business. The department of industrial policy and promotion (DIPP) had proposed a 49% limit in so-called brownfield projects, as opposed to the absence of any cap now, on fears that unfettered acquisitions could drive up the cost of medicines in India.

Similar reports on the topic have appeared in the following portals:

The Economic Times - [Its a Booster for MNC Players as Pharma Stays Free](#) (E-paper link available)

The Economic Times – [Government not to reduce FDI cap in existing pharma companies](#)

The Economic Times – [Under pressure, cabinet defers decision on FDI curbs in pharma](#)

The Times of India - [Govt rejects plan to cut pharma FDI cap](#)

NDTV Profit - [Government rejects proposal to lower FDI cap in existing pharma firms: report](#)

Business Standard – [No change in pharma FDI policy](#)

Business Standard - [Devangshu Datta: As we vote, FIs sit on the fence](#)

The Hindu Business Line - [Govt volte-face on pharma FDI: Health concerns put on the back-burner](#)

The Hindu Business Line - [No change in pharma FDI norms: Sharma](#)

The Hindu Business Line - [Cabinet defers decision on FDI in pharma, construction sectors, again](#)

The Financial Express - [Cabinet rejects industry dept proposal on FDI in pharma](#)

The Financial Express - [Govt rejects proposal to cut FDI cap in pharma firms](#)

Financial Chronicle - [No lowering of FDI cap in brownfield pharma](#)

The Wall Street Journal - [India Backs Off on Restricting Foreign Pharmaceutical Investment](#)

Zee News - [No clear gainers if Pharma FDI is capped](#)

The Asian Age - [Split in govt, move to cut pharma FDI cap on hold](#)

Publication: The Economic Times (Editorial)

Edition: National

Date: November 30, 2013

Headline: [Welcome decision on FDI in pharma sector](#)

Synopsis: It is welcome that the Cabinet has shot down a proposal to restrict foreign direct investment (FDI) in the pharmaceutical sector. India has nothing to fear from FDI in drugs and pharmaceuticals, whether in new plant and capacity or in existing ones. There is no danger of the Indian market being taken over by foreign companies and drugs turning unaffordable for the majority of Indians. Such fears are not just irrational but also counterproductive, with the potential to adversely impact the availability of affordable drugs in the country.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: Business Standard

Edition: National

Date: November 29, 2013

Headline: [IPAB dismisses patent revocation against Kibow](#)

Synopsis: The Intellectual Property Appellate Board (IPAB) has dismissed an application filed by La Renon Health Care Pvt Ltd against a patent granted to the US-based Kibow Biotech Inc., for a probiotic dietary supplement. Kibow Biotech, in a press release, said the IPAB order was related to a granted product patent. The patent granted to Kibow Biotech Inc. is for the invention--"compositions for augmenting kidney function".

Publication: The Hindu Business Line

Edition: National

Date: November 29, 2013

Headline: [IP tribunal upholds US company's product patent](#)

Synopsis: The Intellectual Property Appellate Board has upheld its 2009 decision to grant US-based Kibow Biotech a patent for a probiotic dietary supplement that will augment kidney function, according to a statement by the company.

Publication: The Hindu

Edition: National

Date: November 29, 2013

Headline: [Seed is sovereignty](#)

Synopsis: Suman Sahay, activist and founder of Gene Campaign, in New Delhi said "When the GATT-WTO episode was unfolding, the entire debate was focussed on the product patents in the pharmaceutical sector. But we argued that the real deadly patent demand is on seed. Till then, nobody had realised it because the country was focused on the health sector and also big players were involved in it but it touched a chord somewhere," she feels. As a geneticist, she "could see the game plan then, the legal terms used in the proposal." She was particularly attuned because as a lab scientist in the University of Heidelberg (She obtained her habilitation in human genetics there), she "saw the genetic material coming in all kinds of conditions."

Publication: Equity Bulls

Edition: Online

Date: December 1, 2013

Headline: [Biocon & Mylan Receive Indian Regulatory Approval for Biosimilar Trastuzumab for Treating Breast Cancer](#)

Synopsis: Biocon Ltd has received Marketing Authorization from the Drugs Controller General of India (DCGI) for its biosimilar Trastuzumab being developed jointly with Mylan, for the treatment of Her 2+ metastatic breast cancer. The regulatory approval for biosimilar Trastuzumab in India is an extremely important milestone for Biocon as it is the world's first biosimilar version of Herceptin(R) to be brought to the market. The biosimilar Trastuzumab will be marketed in India under the brand name of CANMAB(TM) by Biocon.

Publication: Equity Bulls

Edition: National

Date: December 1, 2013

Headline: [Venus Remedies becomes first pharma firm to get marketing approval for meropenem in Gulf](#)

Synopsis: Venus Remedies Limited has emerged as the first Indian company to get approval for meropenem in the Gulf with marketing authorisation from the Saudi Food and Drug Authority (SFDA). The company is planning to launch this product in Saudi Arabia, considered one of the most lucrative pharmaceutical markets in the world, early next year.

Publication: The Times of India

Edition: National

Date: November 29, 2013

Headline: [FDA recalls TB drug with wrong dosage](#)

Synopsis: The Pune division of Food and Drug Administration (FDA) has stepped up surveillance and recalled a particular batch of anti-tuberculosis drug 4D and 4D+ from the market following the country-wide recall. While a batch 4D drug was found to have wrong dosage, packs of its stronger variant 4D+ were found to have three pills instead of four in one particular batch.

Publication: Moneycontrol

Edition: Online

Date: November 29, 2013

Headline: [Jubilant Life jumps 10% on US FDA approval](#)

Synopsis: Shares of Jubilant Life Sciences jumped 10 percent on Friday on FDA approval. The drug company received approval from the US health regulator to market generic version AstraZeneca's Seroquel. The drug is used for the treatment of schizophrenia and acute manic episodes associated with bipolar disorder. The abbreviated new drug applications (ANDAs) approval from the US Food and Drug Administration is for Quetiapine Fumarate tablet, generic version AstraZeneca's Seroquel is in strength of 25 mg (base).

Drug Pricing

Publication: The Times of India

Edition: National

Date: December 1, 2013

Headline: [80% of medicines not covered by price control order](#)

Synopsis: About 38 million people in India (which is more than Canada's population) fall below the poverty line every year due to healthcare expenses, of which 70% is on purchase of drugs. Yet, the much-awaited drug price control order (DPCO) 2013, meant to control the price of medicines does not cover over 80% of the medicines in the market. Many drugs crucial for India's disease profile have been left out, which means people are unlikely to see any significant reduction in expenditure on medicines.

Publication: The Hindu Business Line

Edition: National

Date: November 30, 2013

Headline: [Govt to address industry concerns on drug pricing](#)

Synopsis: Pharmaceutical industries highlighted their concerns about the implementation of the new drug price control order and sought more transparency in the pricing mechanism during an interaction with Central Government officials on Friday. At the meeting, convened by the National Pharmaceutical Pricing Authority (NPPA) at the Delhi Institute of Management, the Government assured the industries that their concerns would be addressed while implementing the price control order.

Clinical Trials

Publication: Jagran Josh

Edition: National

Date: November 30, 2013

Headline: [Saurashtra University, the First in Rajkot to Get Registered with DCGI for Clinical Trials](#)

Synopsis: Department of Pharmaceutical Sciences of Saurashtra University (SU) has received approval of clinical studies from Drug Controller General of India (DCGI) in New Delhi. As informed by SU officials, Department of Pharmaceutical Sciences, Saurashtra University in Rajkot is the only PG pharmacy education

in entire region and has taken initiative to register its ethics committee with DCGI and obtain consent for the same. As per the ongoing law, DCGI cannot approve or review of any clinical trials or bioavailability/bioequivalence education in the country, until its ethics committee is not registered with them, told Dr. Aarti Trivedi, Chairman of Ethics Committee, Department of Pharmaceutical Sciences.

Publication: The Times of India

Edition: National

Date: December 1, 2013

Headline: [Help end sufferings of gas-hit: NGOs](#)

Synopsis: Rachna Dhingra, representative of Bhopal Group for Information and Action (BGIA) said that notices by the Supreme Court regarding unethical clinical trials on survivors and punishment to corrupt medical research workers is one of the good things that have happened in 2013.

General Industry

Publication: The Economic Times (Reproduced from PTI)

Edition: National

Date: December 1, 2013

Headline: [India's healthcare sector to grow to \\$ 158.2 billion in 2017: Study](#)

Synopsis: The healthcare sector in India will grow to \$ 158.2 billion in 2017 from \$ 78.6 billion in 2012, a report has said. "The healthcare sector is growing at a 15 per cent CAGR and jumped from \$ 45 billion in 2008 to \$ 78.6 billion in 2012 and expected to touch \$ 158.2 billion by 2017," Equentis Capital said in its report. India's competitive advantage also lies in increased success rate of Indian companies in getting Abbreviated New Drug Application (ANDA) approvals. India also offers vast opportunities in R&D as well as medical tourism, the report said.

Publication: The Times of India

Edition: National

Date: December 2, 2013

Headline: [New branch of medicines to hit market soon](#)

Synopsis: A new domain of medicines from the drug molecules extracted from plants, called as phyto-pharmaceuticals is to hit the market soon in near future. The Ministry of Health and Family Welfare has notified the draft rules on phyto-pharmaceuticals, amending the Drug and Cosmetic Rules, that will form the basis for a regulatory system to evaluate and get approvals of plant based drugs. According to regional coordinator, pharmacovigilance, northern region, Dr Anand Chaudhary, these new rules are open for any kind of comment by people. People can comment on the merits and demerits of the new draft by December 7.

Publication: The Hindu Business Line

Edition: National

Date: November 29, 2013

Headline: [Dabur promoters tie up with UK's Healthcare at Home](#)

Synopsis: The Burman family, promoters of Dabur India, has entered into a joint venture with the founders of UK-based HealthCare at Home, to expand the concept of home healthcare services in India. The two partners said they will invest Rs 200 crore over the next 3-5 years to expand operations in India.

Publication: Pharmabiz

Edition: Online

Date: November 30, 2013

Headline: [UK partners with BioAsia; seeks closer ties with Indian pharma, biotech cos](#)

Synopsis: United Kingdom (UK) has announced its partnership with upcoming BioAsia 2014 and is looking to build closer ties with Indian pharma and biotechnology industry. United Kingdom (UK) which is home to leading pharmaceutical companies like GlaxoSmithKline, AstraZeneca is looking to forge closer ties with India which is considered to be a growing power in Life Sciences industry. As part of this process, UK has now partnered with BioAsia as the Principal Country Partner for the 11th edition of the event, BioAsia 2014. This Asia's largest bio-business forum will be held at the Hyderabad International Convention Centre (HICC) from 17th to 19th February 2014, in Hyderabad.

Publication: Pharmabiz

Edition: Online

Date: November 30, 2013

Headline: [Pharmexcil gearing up for scientific symposium on export policy at 65th IPC 2013](#)

Synopsis: The Pharmaceutical Export Promotion Council of India (Pharmexcil) is gearing up for organising a scientific symposium on pharma export policy at the upcoming 65th Indian Pharmaceutical Congress (IPC) 2013 in New Delhi. The big event is hosted by the Indian Pharmacy Graduates Association from December 20 to 22, 2013 at Amity University Campus, in Noida.

Publication: Tapan Ray Website

Edition: Online

Date: December 2, 2013

Headline: [Public Healthcare Space: Evaluating Three Fresh Edicts](#)

Synopsis: Medicines constitute a significant cost component of modern healthcare systems across the world. However, in India the situation is even worse, whereas per recent studies, drugs contribute as high as around 70 percent of the total treatment cost. This is mainly because overall healthcare system in the country is fundamentally different not just from the developed world, but also from many other developing countries like, China, Brazil, South Africa and Thailand, to name a few.

Access and Affordability

Publication: The Financial Express

Edition: National

Author: Columnist Paul Krugman (New York Times)

Date: November 30, 2013

Headline: [Column: Obamacare's secret success](#)

Synopsis: The law establishing Obamacare was officially titled the Patient Protection and Affordable Care Act. And the "affordable" bit wasn't just about subsidising premiums. It was also supposed to be about "bending the curve"—slowing the seemingly inexorable rise in health costs.

The opinion article has also appeared in The Hindu Business Line - Print and [The Hindu, Online](#)

Publication: The Times of India

Edition: National

Date: December 1, 2013

Headline: [Morphine available to just 1% cancer sufferers](#)

Synopsis: When the winter session of Parliament begins on December 5, millions of cancer patients hope lawmakers will clear a long-awaited amendment that will allow them easier access to morphine. Morphine, one of the best known pain-control medicines, is available to barely 1% of all patients suffering from pain arising out of their cancer or HIV/AIDS infection, say experts. "India has 2.4 million cancer patients who need pain relief and another 2.5 million living with HIV. These patients sometimes suffer unbearable pain that is best relieved by morphine," said Thiruvananthapuram-based Dr M R Rajagopal, who is often referred

to as the father of palliative care in India.

Publication: The Times of India

Edition: National

Date: December 1, 2013

Headline: [HIV-positive patients getting free life-saving drugs double since 2008](#)

Synopsis: The happy news on the HIV epidemic front continues. Just when United Nations AIDS (UNAIDS) has praised India for reducing new HIV infection rate by 57% in a decade, news from Mumbai shows that the number of patients put on life-saving drugs has almost doubled in the last five years. Figures released by the Mumbai District AIDS Control Society (MDACS) on the eve of World AIDS Day show that 36,920 HIV patients in the city have been put on anti-retroviral therapy (ART) over the years. The therapy has been instrumental in changing the perception of AIDS from being a death sentence to a manageable chronic disease. "This is a 96.2% increase in the number of patients taking ART since 2008," said Dr B Adsul, additional project director at MDACS. The numbers show that the AIDS-control programme is spreading wider into the community.

Publication: The Times of India

Edition: National

Date: December 1, 2013

Headline: [Silver jubilee: The beginning of the end of AIDS?](#)

Synopsis: Today is the silver jubilee of World AIDS Day. The first World AIDS day was celebrated 25 years ago. As we celebrate World AIDS Day, there is some good news to report: the rate of HIV infection is declining! Worldwide, 2.3 million people became newly infected with HIV in 2012, down from 3.4 million in 2001. However, there are still an alarming number of people, 35.3 million, living with HIV. In India, the AIDS pandemic brought along with it liberation of sorts. The fact that India and small town India in particular had significant numbers of non-heterosexual people, brought to the fore the ugliness of discriminatory laws such as IPC 377. The fight by some NGOs to ensure that equitable and compassionate access to treatment also reached the panthi, kothi, hijra and kinnar communities, ultimately led to a reading down of the law. The LGBT community in India got a voice and a visibility, thanks to the AIDS pandemic. The government and the authorities could no longer pretend that non-heterosexual people didn't exist in India.

Publication: Daily News and Analysis

Edition: National

Date: December 1, 2013

Headline: [Need law to protect the HIV positive](#)

Synopsis: According to estimates, about 24 lakh Indians are living with HIV, with Karnataka having the third highest prevalence. Lakhs of sufferers demanding a legal protection continue to wait as the HIV/AIDS bill that was formulated six years ago has not received parliamentary consent yet. "We hope the bill that has come back to the health ministry will be presented in the Rajya Sabha during the winter session of the parliament," said Reny Jacob, national advocacy director of World Vision India. The bills cover several crucial aspects of protection for affected people, including one against discrimination, a special provision for women and children, access to treatment and health ombudsman in every district.

Publication: Hindustan Times

Edition: National

Date: November 29, 2013

Headline: [HIV+ people need access, care and confidentiality](#)

Synopsis: Talks about the initiatives taken by the Karnataka Government in order to spread HIV-AIDS awareness among students over the years. The noble intent and the ground reality are poles apart, with Karnataka being just one case among the many similar Indian states. With World AIDS day on December 1, the various stakeholders are eagerly looking forward to how the HIV/AIDS Bill would fare, if and when

tabled in the winter session of Parliament.

Publication: Hindustan Times

Edition: National

Author: Column - Poonam Khetrapal Singh is regional director-elect, WHO, South East Asia region

Date: November 28, 2013

Headline: [Science alone cannot end HIV/AIDS](#)

Synopsis: Scientific breakthroughs have helped us chart an impressive course in the HIV/AIDS response such that in the fourth decade of the epidemic, we are already talking of ending AIDS. Despite the fact that a vaccine for this disease still eludes us and a cure is not yet possible, we have been able to not only control but have also managed to reverse the epidemic in large parts of the globe. For us to reach this stage, contributions have come from a wide variety of stakeholders — governments, funding agencies, development agencies including the United Nations that collaborated and joined forces to support countries in addressing the epidemic and last but not the least, communities which continue to relentlessly fight for people's right to affordable and equitable access to treatment.

Publication: The Asian Age

Edition: National

Date: December 1, 2013

Headline: [Don't trade away access to drugs for financial gain](#)

Synopsis: In the Bangkok meet, India came in for much applause, although the country has 2,100,000 people living with HIV and AIDS, the highest in the Asia and Pacific region. The good news is that the number of new HIV infections among adults in this country have declined by as much as 57 per cent since 2000, according to a new report from UNAIDS, the joint United Nations programme on HIV/AIDS, released at the congress. India is also among the countries stepping up public funding to fund the next phase of the National AIDS Control programme and has publicly committed to financing more than 80 per cent of its national AIDS response from domestic resources from 2014. HIV in Asia and the Pacific, the latest report from UNAIDS, has an entire page devoted to the seven actions that changed the course of India's HIV epidemic.

Publication: Pharmabiz

Edition: Online

Date: November 30, 2013

Headline: [INCLIN Trust sees more HIV patients having access to high quality treatment](#)

Synopsis: INCLIN Trust has viewed that availability of high quality, affordable and patient friendly anti-retroviral (ARVs) therapies has played a vital role in combating the spread of the epidemic in India even as the world still seeks a vaccine and cure for HIV/AIDS. Ahead of the World AIDS Day, experts from across the country have lauded the efforts of the pharmaceutical industry for ensuring a steady supply of innovative therapies for government programmes which currently provide free treatment or at subsidized cost.