



News Updates: October 1, 2014

OPPI- Drug pricing

Publication: The Hindu Business Line (sourced from PTI)

Edition: National

Date: October 1, 2014

Headline: How can you cap drug prices in absence of guidelines, HC asks NPPA (link unavailable, scan attached)

Synopsis: The Delhi High Court on Tuesday asked the National Pharmaceutical Pricing Authority (NPPA) to show the manner in which it is exercising its power to cap prices of non-scheduled drugs in view of the recent withdrawal of the guidelines issued for the purpose. "It is not that you do not have the power for carrying out the exercise, it is the manner in which you exercise it that is being questioned," the Bench said after the counsel for the NPPA contended that withdrawal of the guidelines has not taken away the authority's power to fix prices.

Similar reports in-

The Economic Times- [How are you capping drug prices in absence of guidelines: High Court to NPPA](#)

Business Standard- [How are you capping drug prices in absence of guidelines: HC](#)

Daily News & Analysis- [How are you capping drug prices in absence of guidelines: Delhi High Court](#)

The Free Press Journal- [How are you capping drug prices in absence of norms? HC to NPPA](#)

NDTV- [How Are You Capping Drug Prices in Absence of Guidelines: Court Asks NPPA](#)

NPPA/ Drug Pricing

Publication: Business Standard

Edition: National

Date: October 1, 2014

Headline: [To cap, or not to cap](#) (editorial)

Synopsis: NPPA's power to regulate their prices under "extraordinary circumstances" remains intact. Two, the July list of price caps has not been withdrawn; in that sense, the companies that had been impacted by it have got no relief. But the withdrawal of the May guidelines means that the NPPA cannot announce new price caps on the basis of inter-brand price differences. It is known that the NPPA was contemplating further price caps in categories, such as cancer, HIV/AIDS, tuberculosis, malaria, asthma and so on. Companies that make these medicines can let out a sigh of relief, at least for the time being.

Website: Pharmabiz

Edition: Online

Date: October 1, 2014

Headline: [ATTEMPT TO WEAKEN NPPA](#) (editorial)

Synopsis: The notification issued by the National Pharmaceutical Pricing Authority on July 10 placed price caps on 108 formulation packs of 50 anti diabetic and cardiovascular drugs. Some of these expensive drugs which came under price control following the July order are Gliclazide, Glimepiride, Sitagliptin, Voglibose, Amlodipine, Telmisartan and Rosuvastatin, Heparin and Ramipril. These have an estimated market value of about Rs. 5,500 crore. The NPPA brought these drugs under the purview of DPCO as per a set of internal guidelines issued on May 29 allowing the Authority to control drug prices in public interest. These guidelines empowered NPPA to invoke Paragraph 19 of the DPCO 2013 and extend price control over medicines outside the DPCO list of essential medicines in "extraordinary

circumstances” and in “public interest”. When DPCO 2013 was notified last year, formulations of only 348 drugs were under control keeping many widely used essential medicines outside control. The coverage of drugs under DPCO 2013, thus, impacted only a small fraction of the Rs.72,000 crore domestic pharma market. The NPPA’s move to bring more essential medicines under the purview of price control is in the context of this situation. It has observed that huge inter brand price differences exist in drugs required for treatment of deadly diseases like cancer, HIV, tuberculosis and certain other infectious diseases. NPPA decision to announce price caps again on additional 36 drugs on September 20 is in consideration of the need to make these essential medicines more affordable.

Publication: The New Indian Express

Edition: National

Date: October 1, 2014

Headline: [Drug Industry-Doctor Ties Fan High Medicine Prices](#) (editorial)

Synopsis: While the NPPA has been emasculated, the circumstances that forced it to act have not changed a wee bit. The unethical and anti-competitive pricing practice resorted to by the drug industry is the villain of the piece. The huge difference in the prices of branded drugs and generic drugs tells a story of the kind of collusion between the medical fraternity and the drug industry. As early as 2002, the Medical Council of India had vide its Code of Ethics regulation mandated all the doctors to prescribe generic drugs as far as possible. The regulation is not at all honoured. As a rule, doctors prescribe costly branded drugs because they come under the influence of the drug industry that either indoctrinates them or bribes them.

Publication: Daily News & Analysis

Edition: National

Date: October 1, 2014

Headline: [Cancer drug price goes up from Rs 8,000 to Rs 1.08 lakh](#)

Synopsis: The Union government decision to decontrol prices of 108 drugs -- used to treat tuberculosis, AIDS, diabetes and heart ailments -- has jacked up their prices. In some cases, prices have seen an unbelievable rise. The price of Glivec, an anti- cancer tablet, for example, has risen from Rs 8,500 to Rs 1.08 lakh. Plavix, used to treat blood pressure and heart ailments, will cost Rs 1,615, against the earlier Rs 147. An anti-rabi injection, Kamrab, priced at Rs 2,670, will now cost Rs 7,000.

Publication: Mint

Edition: National

Date: October 1, 2014

Headline: [NPPA pulled up for Dettol price issue](#) (link unavailable, scan attached)

Synopsis: The Delhi high court, on Tuesday, reprimanded the National Pharmaceutical Pricing Authority (NPPA) for not implementing an August 2013 order- which will lead to a rise in prices of antiseptic liquid, Dettol. Saying that NPPA "cannot unilaterally choose to ignore" the August 2013 order of the DoP, Justice Vibhu Bakhru reprimanded the NPPA for not implementing the same. The order has to be complied with in four weeks.

Patent/ IPR/ Compulsory licensing

Publication: Business World

Edition: National

Date: September 30, 2014

Interview: John J. Castellani, president and chief executive officer (CEO), PhRMA

Headline: [‘India Needs To Show It Values Innovation’](#)

Synopsis: The Pharmaceutical Research and Manufacturers of America (PhRMA) is a staunch anti-India lobby in the US. The organisation, which represents leading global biotech and pharmaceutical

manufacturing corporations, had urged the United States Trade Representative (USTR) to downgrade India as a “priority foreign country” in its 2014 Special 301 Report on account of India’s alleged weak Intellectual Property Rights (IPR) rules. If USTR had obliged, India would have invited trade sanctions. PhRMA believes that India is shutting down US companies and appropriating their technology in order to benefit domestic pharmaceutical companies. The organisation wants its members to have a fair say in the market opportunities thrown up by India’s burgeoning 150-million-strong middle-class. John J. Castellani, president and chief executive officer (CEO), PhRMA, talks to BW | Businessworld about the priorities of member companies and what the US pharmaceutical industry expects from Prime Minister Narendra Modi’s meeting with US President Barack Obama.

Publication: Thomson Reuters Foundation

Edition: Online

Date: September 30, 2014

Headline: [India's Modi must resist U.S. pressure on drug patents-MSF](#)

Synopsis: Indian Prime Minister Narendra Modi must not give in to U.S. pressure to change intellectual property laws which allow India to produce generic medicines poor people can afford, the medical charity Doctors Without Borders (MSF) said. Modi, who is visiting the United States to bolster trade and investment ties, has been meeting senior Congressmen and business leaders. He met President Barack Obama at a White House dinner on Monday and the two will hold further talks on Tuesday.

Similar reports in-

Mint- [Narendra Modi must resist US pressure on drug patents: MSF](#)

Business Today- [PM Narendra Modi must resist US pressure on drug patents, says MSF](#)

Deccan Chronicle- [Modi must resist U.S. pressure on drug patents – MSF](#)

Website: Infojustice.org (previously appeared in *The Indian Express* and *Business Standard*)

Edition: National

Date: September 30, 2014

Headline: [Joint Statement on the Proposed Indian IP Policy and the Prime Minister’s Visit to the US](#)

Synopsis: We, the undersigned organisations and individuals, understand that ahead of Prime Minister Narendra Modi’s scheduled visit to the United States, the government has decided to review India’s positions on intellectual property rights (IPRs). We are concerned about the timing that has been chosen to undertake a Ministry-level exercise on India’s IPR policy and apprehend the proposed exercise could become a hostage to the pressures of the US government and companies. Commerce and industry minister Ms. Nirmala Sitharaman, in a press briefing on 8 September indicated that the government would roll out a revised policy on IPRs. She also indicated that this policy would focus on boosting innovation and tone up the overall administration, besides setting up a think tank to strengthen the country’s patent regime. She also said that, *”India does not have an IPR policy. This is the first time we are coming out with an IPR policy. We are very strong in IPR and we certainly want to protect our interest. IPR policy issues have been hanging for quite a long time and the new policy will give direction in terms of protecting IPRs of India.

Modi government

Publication: Business Today

Edition: Online

Date: September 30, 2014

Headline: [Pfizer, Abbott absence at PM breakfast meeting gets noticed](#)

Synopsis: Two of the top 10 US pharmaceutical giants in India by their India business sales - Abbott and Pfizer - did not figure in the guest list for the breakfast meeting with Prime Minister Narendra Modi in the US on September 29. Abbott is the top pharma company by sales in India and Pfizer is the 10th largest, according to AIOCD-AWACS, which ranks drug companies based on their tablet or capsule sales

in India. Pfizer is one of the largest globally by revenues also.

Publication: The Economic Times

Edition: National

Date: October 1, 2014

Headline: [PM's US Visit: Narendra Modi's CEO diplomacy to soon set the cash register ringing](#)

Synopsis: Prime Minister Narendra Modi's breakfast diplomacy with 17 top US CEOs, presiding over ten trillion dollars in assets or revenues, would soon set the cash registers ringing at India's FDI front-desk. Laurence D Fink, CEO at one of the world's largest investment management firms, BlackRock which oversees \$4.32 trillion in assets, assured the prime minister that the firm could facilitate investments worth over \$6 billion into the country by early next year. One of the CEOs who met the PM minutes before Fink, told Modi that his firm is looking to invest over half a billion dollars 'in a short while' to set up a big manufacturing facility in India for injectable drugs.

Publication: The Economic Times

Edition: Online

Date: October 1, 2014

Headline: [Modi-Obama joint editorial: Defining India-US relations in 21st century](#)

Synopsis: The arrival of a new government in New Delhi is the right time to expand collaboration in trade, investment and technology that aligns with India's development goals while sustaining US as the global engine of growth, US President Barack Obama and Prime Minister Narendra Modi said in a joint article in Washington Post on Tuesday. The article that appeared hours before the two sat down in White House for a one-to-one meeting evoked names like Swami Vivekananda, Martin Luther King, Mahatma Gandhi and Henry David Thoreau, and called for exploring ways in which businesses, scientists and governments can partner between the two countries.

Similar report in-

Mint- [Narendra Modi, Barack Obama pledge to boost strategic partnership](#)

Publication: The Economic Times

Edition: Online

Date: September 30, 2014

Headline: [Government launches Rs 1,000 per month minimum pension across the country](#)

Synopsis: Subscribers to the retirement fund EPFO will get a minimum of Rs 1,000 a month from October 1 under Employees' Pension Scheme 1995 (EPS-95) as the government formally launched the programme today. The government will shell out an estimated Rs 1,200 crore to provide for this entitlement. According to EPFO estimates, around 32 lakh pensioners under the scheme, who get less than Rs 1,000 every month as pension, will benefit immediately.

Similar reports in-

The Hindu- [Good days ahead for EPS beneficiaries](#)

The New Indian Express- ['Bring Pensioners Under Health Insurance Scheme'](#)

Publication: The Hindu Business Line

Edition: Thiruvananthapuram

Date: October 1, 2014

Headline: [Disinvestment does not dry up dividend flow, says Nirmala Sitharaman](#)

Synopsis: The Centre has clarified that neither would the disinvestment process deny it dividends from

Central Public Sector Enterprises (CPSEs) nor would the proceeds go towards consumption expenditure. This was conveyed by Nirmala Sitharaman, Union Minister of State for Commerce and Industry, to Sitaram Yechury, CPI (M) leader and MP, who had doubted the rationale of disinvestment in the Rajya Sabha.

Publication: Outlook

Edition: Online

Date: September 30, 2014

Headline: [Govt to Rope In Business Houses, RWAs for 'Clean India'](#)

Synopsis: Government will involve business and industrial chambers, residents welfare associations and NGOs among others to create mass awareness about its ambitious 'Clean India' campaign. Besides, the central government ministries have been asked to be in touch with their counterparts in states and union territories to emphasize upon the need for cleanliness in public places.

Publication: The Times of India

Edition: Chandigarh

Date: October 1, 2014

Headline: ['Swachh Bharat mission is based on building immunity'](#)

Synopsis: The Swachh Bharat mission is based on building immunity and not limited to cleanliness alone. Finding a scientific premise to the mission, Dr Jitendra Singh, union minister of state (independent charge) for science & technology and earth science preferred to give a scientific link to the mission. He was on his first visit to the Institute of Microbial Technology (Imtech). "The mission is related to immunology. We all have lost sight of the basis of immunology. Now, we are coming out with vaccines and drugs which have developed multi-drug resistance," said the union minister.

Publication: The National

Edition: National

Date: October 1, 2014

Headline: [Narendra Modi's toilet drive makes sense](#) (editorial)

Synopsis: No Indian leader ever dared to say what Narendra Modi said last year. Spelling out his ambition to eliminate open defecation by 2019 as part of his "Clean India" drive, Mr Modi told a crowd in Delhi that India should build toilets before temples. This objective makes sense, because more than half of the country's population relieve themselves in the open as many do not have access to toilets at home. This takes a heavy toll on public health and the economy. As The National reported yesterday, a shortage of toilets costs the country more than \$50 billion (Dh183.5bn) a year. Evidence suggests that health issues in childhood have significant effects on adult productivity. The number of people in India missing out on opportunities because of disease in early life is staggering. So it would be fair to assume that improving the sanitary environment will improve outcomes.

Publication: The Indian Express

Edition: National

Date: October 1, 2014

Headline: [Walking, running and flying kites for a cleaner India](#)

Synopsis: The Centre has asked state governments to organise walkathons and marathons, painting competitions and kite-flying events to create awareness on Swachhha Bharat Abhiyan, the nationwide sanitation drive. "State and urban local bodies should organise focused programmes like street plays, local ward level awareness programmes, media campaigns, art/literacy competitions, etc to educate people about the importance of sanitation and the indirect cost to the public from neglecting sanitation in the form of ill health, loss of work and cost towards medical treatment," the Ministry of Urban Development has said in exhaustive guidelines issued to all central ministries and state departments.

Clinical trials

Publication: Wonder Woman (India Today Group)

Edition: Online

Date: September 30, 2014

Headline: [Spare the kids in clinical trials](#)

Synopsis: We need to ask crucial questions about the safety of our children in clinical trials. Here's what you should know. The multi-party Parliamentary Committee on Health and Family Welfare has castigated several government agencies for allowing the use of Indian children and adolescents by foreign agencies in determining the safety and efficacy of new drugs including vaccines such as Human Papillomavirus (HPV). In its report tabled in both houses of Parliament, the Committee has pointed to serious lapses on several counts when Program for Appropriate Technology in Health (PATH), an American agency, was allowed to administer HPV vaccines to thousands of children in Andhra Pradesh and Gujarat. At least 7 young girls died following vaccinations. The major findings are extremely worrying: PATH set up an office in New Delhi without mandatory approval from Ministry of External Affairs and Home Ministry. Security and intelligence agencies failed to notice the violation. In its financial statement, PATH had claimed that it received funding from the Indian Ministry of Health and Family Welfare.

Drug quality

Website: Pharmabiz

Edition: Online

Date: October 1, 2014

Headline: [CDSCO upgrades manpower to implement GMP across manufacturing facilities in the country](#)

Synopsis: The Central Drug Standards Control Organization (CDSCO) has started deputing drug inspectors as observers to carry out joint inspections on an event of inspection from an international regulator. The exercise done in coordination with state drug regulators is meant to monitor manufacturing plants on GMPs and equip drug inspectors on enforcing its compliance across the country. Following which, around 80 drug inspectors have been recruited at the CDSCO in the past one year. A total of additional 1195 posts have been sanctioned for the upgradation of manpower and labs under the 12th five year plan. Central Government has allocated Rs. 900 crore for enhancing manpower and capacities of minilabs at port offices and mobile labs at CDSCO level.

General Industry

Publication: The Economic Times

Edition: National

Date: October 1, 2014

Headline: [ET Awards 2014: Sun Pharma's Dilip Shanghvi is Business Leader of the year](#)

Synopsis: A quarter of a century ago, while courting the girl who would later become his wife, Dilip Shanghvi told her that if all went well his company would hit a turnover of Rs 1 crore. He was trying to impress Vibha at the time, Shanghvi says jokingly now. Shanghvi, who turns 59 on October 1, was listed by Bloomberg as the world's richest pharma billionaire with a net worth of \$17.2 billion this August. The low-key, but persistent, managing director of Sun Pharmaceutical Industries is a self-made billionaire who in the last decade has changed the face of Indian pharma. His knack for picking up distressed assets and turning them around inspires both awe and envy among competitors. But even that reputation hadn't prepared the market for the April announcement of Sun taking over Ranbaxy Laboratories for \$3.2 billion. The acquisition, for which approvals are being sought, will create a company with combined sales of Rs 24,000 crore. The deal has also given rise to another buzz and hope in pharma circles, that Sun could one day dislodge Israel's Teva Pharmaceutical Industries as the world's biggest generic drug maker. With Shanghvi at the helm, it all seems possible.

Publication: The Economic Times

Edition: National

Date: October 1, 2014

Headline: [Charity and Big Business Make a Good Mix](#)

Synopsis: Until he stepped down from an active role at Cipla, Yusuf K Hamied, the patriarch of Indian pharma, continued to do what he does best: busting the patents of multinational drug companies and, in the process, making essential medicines affordable. Hamied, 78, retired as Cipla's managing director in February last year after spending 52 years in building the company, one of India's top drug makers. He remains the company's chairman while a professional set of managers handles its operations. Hamied came to the global limelight in 2001 when he cut the prices of HIV drugs to a fraction of the prices charged by Western manufacturers. He did something similar in 2012, when he decided to unsettle the market for cancer drugs. The industry reacted with shock as Cipla reduced the price of key cancer drugs by as much as 75%.

Website: Pharmabiz

Edition: Online

Date: September 30, 2014

Headline: [Trial court denies injunction to BMS against Mylan from blocking access to generic HIV drug in Venezuela](#)

Synopsis: In a huge relief to scores of HIV patients across Venezuela, on 26th September a Trial Court in Hyderabad denied an interim injunction to Bristol-Myers Squibb (BMS). On denying injunction the judge has expressly ruled that BMS has not made out a prima facie case of infringement and that the granting the injunction affects people living with HIV. Emboldened by the series of ex-parte injunctions granted by Indian courts against generic manufacturers, BMS represented by the law firm Anand & Anand, sued Mylan in Hyderabad in August of this year to prevent export of Atazanavir to Venezuela. There are no product patents in India or in Venezuela for Atazanavir itself, but BMS used two secondary process patents granted in India to try and obtain an ex-parte injunction.

Website: Reuters

Edition: Online

Date: September 30, 2014

Headline: [France uses tax to put pressure on hepatitis C drug prices](#)

Synopsis: France will tax drugmakers whose costly hepatitis C drugs threaten to throw off course its healthcare budget, the government has said, heaping pressure on pharmaceutical companies like Gilead Sciences to cut their prices. The Socialist government said it had designed a "progressive contribution scheme" ensuring all patients can access new and more effective treatments against the liver-destroying virus, while limiting the burden of these drugs on state finances.

Website: Pharmabiz

Edition: Online

Date: October 1, 2014

Headline: [Medical devices industry demands de-listing of Schedule M-III from Schedule M](#)

Synopsis: The medical devices industry wants the government to de-list Schedule M-III from Schedule M stating that there is lot of ambiguity and confusion within the given requirements. They also insisted that to overcome and properly address the needs of the sector, the government should amend the existing Schedule M-III to comply with IS 15579/ISO 13485 quality management system requirements for regulatory purposes. Even though law clearly specifies Schedule M for pharma, Schedule M II for cosmetic and Schedule M III for medical devices, industry contends that the use of word 'and' is leading to unnecessary debate and avoidable conflict between the regulators and the industry. The Association of Indian Medical Device Industry (AIMED) pointed out that this is because most of the inspectors

incorrectly insist additional compliance to Schedule M as well which is an overkill for terminally sterilised medical devices.

Publication: Deccan Herald

Edition: National

Date: October 1, 2014

Headline: [Recommending Desai a disgrace](#)

Synopsis: Normally the prospect of an Indian heading a world body of professionals in any field should be a matter of pride for Indians. But it does not enhance the reputation of the medical community in India and its representative bodies like the Indian Medical Association (IMA) and the Medical Council of India (MCI) that a former MCI president, Ketan Desai, may soon be the head of the World Medical Association (WMA). It may, in fact, cast a shadow on the credentials of these bodies which are expected to ensure that their members follow the most ethical and professional norms of conduct. Desai has been controversial and faces serious charges that it was wrong on the part of the IMA to recommend his name for the WMA position.

Website: Reuters

Edition: Online

Date: October 1, 2014

Headline: [Drug, medical device companies paid billions to U.S. physicians, hospitals in 2013: data](#)

Synopsis: U.S. doctors and teaching hospitals received \$3.5 billion from pharmaceutical companies and medical device makers in the last five months of 2013, according to the most extensive data trove on such payments ever made public. The payments, disclosed by the Centers for Medicare and Medicaid Services (CMS) on Tuesday, include consulting and speaking fees, travel, meals, entertainment and research grants. The names of the recipients of about 40 percent of the payments reported by companies were withheld because CMS had concerns about data inconsistencies.