



**News Updates: August 2-4, 2014**

**NPPA issue**

**Publication: Business Standard**

**Edition: National**

**Date: August 4, 2014**

**Headline: [Drugmakers reap benefits of pricing gap](#)**

**Synopsis:** Even as pharmaceutical companies are opposing the latest regulatory move to keep a check on inter-brand price difference, market data show that in some cases the maximum retail price (MRP) of various brands of the same medicine varies by as much as 1,700-1,800 per cent. That leaves a huge profit margin for drug firms even after paying wholesalers and retailers. Data also depicts pricing parity is more significant between brands sold by domestic manufacturers and those marketed by multinational firms. While most multinationals attribute high prices of their products to better quality, standard procedures and efficacy, industry experts and regulatory authorities say the difference in MRP is due to higher cost incurred in marketing and promotion coupled with better profit margins.

**Publication: The Economic Times**

**Edition: National**

**Date: August 2, 2014**

**Headline: [High Court notice to NPPA on plea against price cap on non-scheduled drugs](#)**

**Synopsis:** The Delhi High Court today sought response of the National Pharma Pricing Authority (NPPA) on a plea by an organisation of drug manufacturers, challenging the drug regulator's July 10 notification that brought over 100 medicines under price control. A bench of Justice Vibhu Bakhru, however, refused to allow Organisation of Pharma Producers of India's (OPPI) interim plea seeking a stay or status quo order preventing the government from taking any further steps in pursuance of its notification.

**Publication: Mint**

**Edition: National**

**Date: August 2, 2014**

**Headline: [HC notice to NPPA on plea against price cap on non-essential drugs](#)**

**Synopsis:** The Delhi high court on Friday sought response of the National Pharmaceutical Pricing Authority (NPPA) on a plea by an organization of drug manufacturers challenging the drug regulator's 10 July notification that brought over 100 medicines under price control. A bench of justice Vibhu Bakhru, however, refused to allow Organization of Pharmaceutical Producers of India's (OPPI) interim plea seeking a stay or status quo order preventing the government from taking any further steps in pursuance of its notification.

**Publication: The Financial Express**

**Edition: National**

**Date: August 2, 2014**

**Headline: [Delhi High Court delivers setback to OPPI, refuses stay on drug pricing notification](#)**

**Synopsis:** The Delhi High Court on Friday turned down a plea of the Organisation of Pharma Producers of India (OPPI) to stay a recent notification of the National Pharmaceutical Pricing Authority (NPPA) bringing 108 drug formulations used to treat diabetes and cardio-vascular disorders under pricing control. Further, it also shot down OPPI's demand for a restraint on the NPPA from issuing any subsequent orders in this regard. Recently, on July 10, the NPPA had capped the prices of these formulations which account for 6% of the the Indian pharmaceutical market, or R5,500 crore, according to the All-India Organisation of Chemists and Druggists-

AWACS, the traders' outfit.

**Publication: The Hindustan Times**

**Edition: National**

**Date: August 2, 2014**

**Headline: HC notice to NPPA on plea over price cap on 100 drugs (link unavailable, scan attached)**

**Synopsis:** Delhi High Court on Friday sought response of the National Pharma Pricing Authority on a plea by drug manufacturers challenging the notification that brought over 100 medicines under price control.

**Similar reports in-**

Free Press Journal- [HC refuses to stay NPPA order capping price of 108 drug formulations](#)

The Hans India- [Delhi HC notice to NPPA on price cap \(link unavailable, scan attached\)](#)

Moneylife- [Delhi HC refuses a stay on NPPA order fixing drug prices](#)

Zee News- [Delhi HC refuses to stay order fixing prices of over 100 drugs](#)

**Publication: The Hindu Business Line**

**Edition: National**

**Date: August 2, 2014**

**Editorial: Aarati Krishnan, Deputy Editor, Head of Research at Business Line**

**Headline: [Regulating for the minority](#)**

**Synopsis:** The fracas over the Government's recent decision to cap the prices of diabetes and cardio-vascular drugs makes one wonder at the topsy-turvy world of Indian regulations. How did it come about that sectors such as financial services, which impact only a fraction of the population, have such elaborate and water-tight regulations for consumer protection, while those such as healthcare and real estate, which have a large impact on the day-to-day lives of most people, get by with hardly any regulatory oversight?

**Website: Pharmabiz**

**Edition: Online**

**Date: August 2, 2014**

**Headline: [Court orders drug cos to maintain status quo on NPPA July 10 notification on price control, case adjourned to Aug 12](#)**

**Synopsis:** The Bombay High Court has adjourned the Indian Pharmaceutical Alliance (IPA)'s case against National Pharmaceutical Pricing Authority (NPPA) to August 12 for bringing 108 drug formulations under price control. However, the court has asked the drug companies to maintain status quo. In the case filed last week, the IPA had challenged the national drug price regulator's controversial notification dated July 10 in which the NPPA had brought 108 drug formulations in the diabetes and cardiovascular segments under price control under Paragraph 19 of the Drugs Price Control Order (DPCO), 2013.

#### Patents/ Compulsory licensing/ IPR

**Publication: Mint**

**Edition: National**

**Date: August 3, 2014**

**Headline: [CCI to scan drug patent settlements](#)**

**Synopsis:** The country's competition regulator may examine details of patent settlements being negotiated between foreign branded medicine companies and local generic drug makers as these agreements may restrict the access of cheaper drugs to the sick. The cases which the Competition Commission of India (CCI) is likely to review include the patent deal between Swiss drug maker F Hoffmann-La Roche Ltd and Cipla Ltd on lung cancer drug erlotinib, and the one between US-drug multinational Merck Sharp and Dohme Corp. (MSD) and India's Glenmark Pharmaceuticals Ltd on a new diabetes drug called sitagliptin.

**Publication: Daily News & Analysis**

**Edition: National**

**Date: August 1, 2014**

**Opinion piece: Mark Elliot, Executive Vice President, US Chamber of Commerce's Global Intellectual Property Center**

**Headline: [Intellectual property can fuel economic growth](#)**

**Synopsis:** The country whose political leadership delivers the strategy for sustained investment, job creation, and innovation has the world at its feet. India may have found its champion. In recent years, entrenched special interests, whose political strength influenced government policy to close markets to global competition, held back India's tremendous economic potential. A hostile environment for intellectual property and limited investment stymied innovation. The resulting uncertainty hampered growth and job creation, especially in the cutting-edge industries where India, with its abundance of skilled and educated workers, should thrive.

**Publication: Business Standard**

**Edition: Online**

**Date: July 31, 2014**

**Headline: [Protest over pressure on India to strengthen IPR](#)**

**Synopsis:** Hundreds of activists Thursday staged a protest here over pressure by Western nations on India to strengthen intellectual property rights, which has the potential to limit the production of life-saving generic medication. Gathered under the banner of AIDS Healthcare Foundation (AHF), the activists demanded at a rally at Jantar Mantar that India should not sign the agreement on Trade Related Aspects of Intellectual Property Rights-plus (TRIPS-plus), which can cut off the potential supply of cheaper generic medicines that can save lives, especially when the original branded products are priced so high that very few can afford them.

#### Clinical trials

**Publication: The Economic Times**

**Edition: National**

**Date: August 2, 2014**

**Headline: [Clinical trial approval process may go online](#)**

**Synopsis:** The Drug Controller General of India's office is planning to shift the process of approving clinical trial applications online. Every trial would be accorded a unique identity number and pharmaceutical companies, ethics committees, doctors or investigators conducting trials would be asked to regularly update information in the online database, including patients' personal details, serious adverse effects that they may suffer and compensation paid out to them by companies, according to a draft proposal firmed up by the drug regulator earlier this week.

#### FDA

**Publication: The Economic Times**

**Edition: National**

**Date: August 3, 2014**

**Headline: [Indian drugmakers to pay higher facility fees on US hike](#)**

**Synopsis:** Drugmakers from India, the biggest source of medicines to the US, may soon have to cough up 12-15 per cent more in annual facility fees as the Food and Drug Administration (FDA) has announced new rates. The US laws authorise the drug and health watchdog to assess and collect user fees for certain applications and supplements for human generic drug products. The new rates, applicable on companies from all nations, are effective from October 1 and will remain in force through September 30, 2015, as per a communication from FDA.

**Similar reports in-**

**Mint- [Indian drug makers to pay higher facility fees to USFDA](#)**

**Business Standard-** [Indian drugmakers may have to cough up higher facility fee](#)

**The Hindu Business Line-** [US pharma regulator cuts drug filing fee by 8%](#)

**The Financial Chronicle-** Indian drugmakers to pay higher facility fees on US hike (link unavailable, scan attached)

**Deccan Herald-** [Indian drugmakers to pay higher facility fees on US hike](#)

**Outlook-** [Indian Drugmakers to Pay Higher Facility Fees on US Hike](#)

**Website:** Pharmabiz

**Edition:** Online

**Date:** August 2, 2014

**Headline:** [US FDA issues draft norms on regulatory submissions in electronic format, industry lauds move](#)

**Synopsis:** The US Food and Drug Administration (FDA) has issued a draft guidance for the pharma and biotechnology industry to provide regulatory submissions in electronic format. This would be related to certain human pharmaceutical product applications. The companies will now have to adopt the eCTD (electronic-Common Technical Document) specifications. The industry has appreciated this draft and sees that this effort by the global regulatory authority would create transparency in submissions, efficient and faster turnarounds. The technical specification documents of the guidelines indicates how sponsors and applicants must organize the content they submit to the USFDA via electronic mode under section 745A(a) of the FD&C Act. When finalised, this guidance will supersede the regulation for industry titled 'Providing Regulatory Submissions in Electronic Format Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications' that was issued in June 2008.

#### WTO/ Modi government

**Publication:** The Economic Times

**Edition:** National

**Date:** August 4, 2014

**Headline:** [Narendra Modi to take up WTO issues with Barack Obama](#)

**Synopsis:** Prime Minister Narendra Modi's upcoming visit to the US could be significant as India hopes to take trade talks forward when the World Trade Organization (WTO) meets in September after the summer break, signalling its commitment to the multilateral trading system. India will try to engage with other countries during the August break to get stronger backing for its proposal of finding a permanent solution to the issue of public stockholding for food security by December 31.

**Publication:** Mint

**Edition:** National

**Date:** August 4, 2014

**Opinion piece:** W.P.S. Sidhu is senior fellow for foreign policy at Brookings India and a senior fellow at the Center on International Cooperation, New York University

**Headline:** [A transformative India-US dialogue?](#)

**Synopsis:** Opinion on the recently concluded fifth India-US strategic dialogue ranged from it being a dramatic "transformative moment" to it making too little progress and being too late. The reality, as always, is somewhere in between—while the dialogue certainly put India-US relations back on track it did not achieve a dramatic breakthrough. This is not an insignificant achievement considering that India's parochial stand, which led to the collapse of the crucial World Trade Organization (WTO) talks, could easily have wrecked the bilateral dialogue. Instead, the two sides managed to insulate their talks from the WTO fallout and produced a joint statement reflecting their widening and deepening relationship.

**Publication:** Daily News & Analysis

**Edition:** National

**Date:** August 3, 2014

**Headline:** [India-US ties at turning point](#)

**Synopsis:** US secretary of state, John Kerry, was in India last week for his first formal interaction with the newly elected Prime Minister Narendra Modi and his government. This was the first US Cabinet-level visit to New Delhi with the Modi government, and Kerry, along with the Indian external affairs minister, Sushma Swaraj, co-chaired the fifth round of India-US Strategic Dialogue on July 31. This meeting was aimed at laying the groundwork for the visit of the Indian Prime Minister to the United States in September. Describing the post-May 2014 landscape in India as “a potentially transformative moment” and calling India “an indispensable partner for the 21st century,” Kerry has suggested that deepening America’s ties with India is a “strategic imperative.”

**Publication:** The Times of India

**Edition:** Online

**Date:** August 3, 2014

**Opinion piece:** Gurcharan Das

**Headline:** [Two months on, mantra’s clear: Less talk, more action](#)

**Synopsis:** It’s been a little over two months since the Modi sarkar came to power. Too soon, perhaps, for a definitive assessment, but there are signs of change; patterns are emerging; and even hints of a larger picture. Where we had expected discontinuity there is surprising continuity. This may say something about the evolution of authority, a maturing of the Indian state. Those who expected big bang reforms are disappointed and those who feared an intolerant autocracy are reassured. Modi himself has been remarkably silent. He has been busy getting things done — those who act often say little. Here is a brief inventory with positive and negative examples.

**Publication:** Business Standard

**Edition:** National

**Date:** August 4, 2014

**Opinion piece:** Mihir S Sharma

**Headline:** [Modi, the swadeshi PM](#)

**Synopsis:** There is reason to feel a certain sense of betrayal if you were indeed naïve enough to believe the Bharatiya Janata Party’s claims that it would reduce prices within a short while of being elected. Inflation, especially food inflation, isn’t a lazy bureaucrat. It isn’t something that will start coming in early following a stern glance from a Strong Leader. It’s a structural problem that will take some time to solve. If you believed anyone’s claims otherwise, then you only have yourself to blame. It is not these people’s reaction that puzzles me.

**Publication:** The Wall Street Journal

**Edition:** National

**Date:** August 4, 2014

**Headline:** [Modi’s Trade Barricade](#)

**Synopsis:** Narendra Modi may prove to be a reformer of India’s domestic economy, but the new Prime Minister is playing the spoiler at the World Trade Organization. Thursday was the deadline to approve the protocol to implement a trade facilitation agreement struck last December in Bali, and Mr. Modi effectively vetoed a deal that would have helped Indian exporters. This is a disaster for his country’s poor. It is also a disaster for the WTO, which needed the accord to revive the stalled Doha Round of talks, underway since 2001. Bali was an attempt to break off a manageable chunk of the larger agenda. To help them lower nontariff trade barriers, developing nations were to receive aid and technical assistance.

**Publication:** The New Indian Express

**Edition:** National

**Date:** August 4, 2014

**Headline:** [US Must Get Used to 'India-first Policy' \(editorial\)](#)

**Synopsis:** India has done well not to buckle under pressure from the US on the WTO’s trade facilitation agreement. The agreement has been nullified by India and a few countries not ratifying it before July 31. US secretary of state John Kerry was neither diplomatic nor truthful when he said India’s refusal to sign the trade

deal had undermined its image. He and his colleague commerce secretary Penny Pritzker who met prime minister Narendra Modi in Delhi last week were clearly told that Western nations should understand the peculiar problems of developing countries like India—a fitting reply to their pressure tactics.

#### Health ministry

**Publication:** Mint

**Edition:** National

**Date:** August 3, 2014

**Headline:** [Govt's health policy to lay emphasis on Ayurveda: Harsh Vardhan](#)

**Synopsis:** Union minister for health and family welfare Harsh Vardhan on Sunday said the government would work towards enhancing Ayurveda's global acceptance as evidence-based medicine. Speaking to reporters at Haridwar after laying the foundation stone of a global museum of Ayurveda and herbal medicine at yoga guru Baba Ramdev's Patanjali yoga pitha, he said that the government's health policy is going to lay primary emphasis on the Ayurveda Siddhanta for the first time since 1947.

#### Similar reports in-

The Times of India- [Government's health policy will lay emphasis on Ayurveda: Vardhan](#)

Business Standard- [Ayush to get a boost: Health minister](#)

The New Indian Express- [Ayurveda to Receive Centre's Top Billing](#)

The Asian Age- [AIIMS to have ayurveda department, says Harsh Vardhan](#)

Outlook- [Govt's Health Policy Will Lay Emphasis on Ayurveda: Vardhan](#)

**Publication:** The New Indian Express

**Edition:** Online

**Date:** August 3, 2014

**Headline:** [Vardhan Blasts MCI for Cancellation of Seats](#)

**Synopsis:** Union Health Minister Harshvardhan on Saturday criticised the Medical Council of India (MCI) for taking an adversarial stand on students while cancelling the seats in medical colleges. This has led to the loss of 1,170 medical seats in the 2014-15 academic year, thereby nipping in the bud the dreams of many meritorious candidates. Reacting to the July 31 Supreme Court Order dismissing the Ministry of Health plea for modification of the time schedule for granting approvals to new colleges and renewal of permission to existing seats in old colleges Vardhan said, "Instead of supporting our plea in court, I am surprised the MCI opposed it. This makes me wonder whose side they are on."

#### Similar reports in-

The Asian Age- [Harsh Vardhan slams 'anti-student' Medical Council of India](#)

Daily News & Analysis- [Health Minister Harsh Vardhan says "MCI's autonomy needs human face"](#)

#### FDI- Insurance

**Publication:** The Economic Times

**Edition:** Online

**Date:** August 4, 2014

**Headline:** [Government initiates efforts for consensus on Insurance Bill](#)

**Synopsis:** As part of efforts to reach a consensus over the controversial Insurance Bill, the government today took the initiative of meeting opposition leaders in Rajya Sabha where the measure's consideration has been deferred. Finance Minister Arun Jaitley and Parliamentary Affairs Minister M Venkaiah Naidu are meeting the leaders in the wake of nine opposition parties giving a notice to Rajya Sabha Chairman Hamid Ansari for referring the bill to a Select Committee.

#### Similar reports in-

The Times of India- [Govt to hold talks with parties on insurance bill today, may move it on Tuesday](#)

The Hindu- [Govt seeks consensus on Insurance Bill](#)

Daily News & Analysis- [Government fails to build consensus with opposition over Insurance Bill](#)

The Financial Express- [Centre likely to keep insurance bill off Rajya Sabha today](#)

## Public Health

**Publication:** The Hindustan Times

**Edition:** National

**Date:** August 3, 2014

**Opinion piece:** Amarjeet Sinha is a civil servant

**Headline:** [NHAM is the next logical step after NRHM](#)

**Synopsis:** The NDA government is considering rolling out a National Health Assurance Mission to reduce out-of-pocket expenditure on healthcare by the common man. Health is a State subject and the state's ownership and thrust on governance determines its success. This is the lesson from the National Rural Health Mission (NRHM). Before assuming insurance as assurance, there is a need to appreciate the problems in healthcare due to information asymmetry, weak regulation, and possible market failures.

**Website:** Niti Central

**Edition:** Online

**Date:** August 2, 2014

**Headline:** [India's child mortality problem is far from over](#)

**Synopsis:** India has come long way as far as providing healthcare services is considered. But despite much success on that front, 50 per cent of India's 400 million children are malnourished, a UN study says. According to it, despite several health-improvement schemes and programmes in the last 30 years, children continue to die because of early childhood diseases, inadequate newborn care and childbirth-related causes. More than two million children die every year from preventable infections, including pneumonia, diarrhoea and measles. It is well known that India has higher rates of malnourished children than even sub-Saharan Africa. Malnutrition remains pervasive across the States. According to Integrated Childhood Development Services (ICDS) that were compiled by State Governments, there has been a significant improvement in the normal category of child nutrition but non-implementation of policies has been a cause for many death across the nation.

## General Industry

**Website:** Reuters

**Edition:** Online

**Date:** August 1, 2014

**Headline:** [U.S. top lawyer calls for greater transparency over execution drugs](#)

**Synopsis:** Attorney General Eric Holder is calling on states to be more transparent about the drug cocktails used in executions in the wake of a series of botched lethal injections that have renewed a national debate over the death penalty. States that impose capital punishment have turned to new suppliers of chemical combinations for lethal injections after European drug makers objected to having their products used for that purpose.

**Publication:** The Indian Express

**Edition:** National

**Date:** August 3, 2014

**Headline:** [Costly cure](#)

**Synopsis:** A \$1,000-per-pill drug that insurers are reluctant to pay for has quickly become the treatment of choice for a liver-wasting viral disease that affects more than three million Americans. In less than six months, prescriptions for Sovaldi have eclipsed all other Hepatitis C pills combined, according to new data from IMS Health. The prospect of a real cure, with fewer nasty side effects, is enticing thousands of patients to get treated for the first time. But clinical and commercial successes have triggered scrutiny for the drug's manufacturer, California-based Gilead Sciences Inc, which just reported second-quarter profits of \$3.66 billion, a net margin of

56 per cent.

**Publication: The Hindu Business Line**

**Edition: National**

**Date: August 4, 2014**

**Headline: [The tale of Pfizer's Thane plant](#)**

**Synopsis:** Two weeks. That is the window that multinational drugmajor Pfizer's management and its workmen at the Thane plant have to sort out their differences and avert a full fledged shutdown. Pfizer had said, on Friday, that it had been forced to issue a lockout notice at its Thane manufacturing plant to ensure the safety of its colleagues. "There have been multiple incidents of indiscipline, threats to our management personnel as well as attempts to disrupt production lines by certain workmen," Pfizer had said in its statement. The plant employs 212 workmen. But the disruption would not affect medicine supplies, it had added. A lockout notice legally gives both sides two weeks to iron out differences, following which it could lead to a shutdown or the court if the situation is unresolved, employees familiar with the development said. In recent years, labour issues have been cropping up in sectors such as the automotive industry. And this time, the fate of the multinational drug company's plant and its employees hangs in balance.