1. **Wockhardt, Alembic challenge NPPA's price revision move in Delhi HC** – Economic Times

Pharmaceutical companies Wockhardt and Alembic have challenged in the Delhi High Court the National Pharmaceutical Pricing Authority's recent moves related to fixation and revision of prices of medicines. According to a lawyer representing one of the companies, there are no provisions in the Drugs Price Control Order (DPCO) that allow NPPA to enforce notifications dated March 2 and 29. The notifications state that manufacturers with scheduled formulations having a maximum retail price (MRP) lower than the revised ceiling price shall make corresponding reductions in their MRP according to the annual wholesale price index (WPI). While NPPA's notifications mention that the decision is as per the provision of paragraph 16(4) of DPCO, the lawyer said: "According to the DPCO, (the company) is only obligated to maintain the existing price". NPPA will contest the case in the court.

2. **Not aware of adverse findings about manufacturing units of Ranbaxy: Sun Pharma** – Economic Times

Sun Pharma said it wasn't aware of any adverse findings related to the manufacturing plants of Ranbaxy Laboratories — which it acquired in 2014 — that are said to be part of an affidavit filed in the Supreme Court by the regulator. The affidavit was submitted by the Drug Controller General of India (DCGI) following a public interest litigation (PIL) filed by activist-lawyer ML Sharma. A media report had said this contained the references to the Ranbaxy plants based on observations made in June-July 2013. Sharma filed the PIL in February seeking closure of Ranbaxy's three manufacturing plants in India. The Singapore arbitration court last week asked the Singh brothers to pay Rs 2,562 crore to Daiichi Sankyo as compensation for the losses it sustained on account of violations said to have occurred under the previous ownership. Whistleblower Thakur has said he will consider joining Sharma's PIL against the company. His petition seeking reform of drug regulation in India had been turned down by the Supreme Court in February.

3. **Centre summarises stand on FDC ban before Delhi HC** – Business Standard

The Central government finally summarised its defence today in the Fixed Dose Combination (FDC) drug ban by which it had prohibited 344 FDCs from being produced and marketed in March of this year. In its hearing, the Central government concluded its three-day long argument justifying the ban, centered on the grounds of public safety and pharmaceutical efficacy. While defending the necessity of government supervision, the counsel stressed on the dynamic nature of the pharmaceutical industry and drew from the Kokate Committee Report, upon which the subsequent action was taken, which states that: "In the field of medicine, no data is final and is always open to review. What was acceptable a few years ago may not be so now." The opposition led the presiding Justice End law to remark, "You (Central Government) have banned the drugs without giving an opportunity for approval (or re-approval). That is what is troubling me. He explained that the government had requested for data numerous times

before conducting the evaluation and no one could claim to be left unaware. "If they (the companies) chose not to come, they cannot be given benefit for their own wrong-doing" the counsel said. "Even if they had an NOC or approval, it was still incumbent on them to act in public interest," Jain further added. The court has listed the matter again for hearing on May 19 for petitioner rebuttals.

4. **Gilead patent on Sofosbuvir a setback for health groups, but they vow to fight on** – Times of India
   A day after US company Gilead was granted a patent on hepatitis C medicine, sofosbuvir, patient groups and companies are planning to challenge it. I-MAK and health advocates around the world agree that sofosbuvir does not deserve a patent, and will be launching an appeal to the decision. The order may block a sustainable supply of key raw materials (APIs) for producing the drug in countries like Egypt, Bangladesh and Pakistan, and hence affect supply of affordable drugs, particularly in those countries, health activists say. Organizations like Sankalp Rehabilitation Trust, Tahir Amin of Initiative for Medicines, Access & Knowledge have condemned the patent approval for Gilead.

5. **Government plans to fund projects in pharamcogenomics to expand scope of PvPI** – Pharmabiz.com
   Following setting up of a task force to link Pharmaco-vigilance Programme in India (PvPI) with pharmaco-genomics, the government is now planning to get funding on project mode to help expand the scope of pharmaco-vigilance in India. With this, PvPI will include pharmaco-genomics under it as a part of its scientific component to address concerns of vulnerable populations susceptible to adverse drug events induced by a certain drug triggered due to genetic factors. An amount of around Rs.50 lakh is being planned to be reserved with help from the Union health ministry in the initial phase to expand the scope of pharmaco-vigilance and include pharmaco-genomics as its scientific component. Said a senior pharmaco-vigilance official, “This would be a major breakthrough as PvPI is currently restricted till clinical data collection on adverse drug reactions (ADRs). Meanwhile, with the task force in place, projects will also be easily funded now.” Central Drugs Standard Control Organisation (CDSCO), under the Union health ministry had initiated a nation-wide PvPI in July 2010. Dr Y K Gupta is credited to have started PvPI in 2010 at AIIMS with support from CDSCO and government of India. This got further expanded and for administrative reasons was shifted to Ghaziabad based Indian Pharmacopoeia Commission.