1. **Burden of pricey hepatitis C drugs heaviest in Eastern Europe** – Reuters

An analysis of prices for two Gilead drugs by World Health Organization (WHO) experts published on Tuesday found that while U.S. prices were higher in dollar terms, parts of Europe paid considerably more in "purchasing-power parity" terms. The PPP-adjusted price in Poland of a treatment course with Gilead's Harvoni was $118,754, against $72,765 in the United States, the study found, and it would cost 190.5 percent of the country's total drugs budget to treat all Polish patients. Another Gilead drug, Sovaldi, had a similar nominal price in both Norway and Slovakia, but on a PPP basis the price was more than twice as much in Slovakia. "If you want to treat all patients with hepatitis C, then the prices countries are being asked to pay - even after price negotiations - are still way too high," said study author Suzanne Hill, the WHO's director of essential medicines. The cost of Gilead's hepatitis C drugs has been contentious since the U.S. approval of Sovaldi in 2013, although the company has taken several steps to offer discounts and provide access programs. This includes allowing Indian drug companies to manufacture much lower-cost versions of the medicines for sale in developing countries.

2. **Time for India to be innovator nation in bio-pharmaceuticals: Expert** – Economic Times

Observing India's potential, Michael Rosenblatt, executive vice president of Merck & Co, one of the world's largest pharmaceutical companies, said yesterday that India can play a "leading role" in collaborative research in biopharmaceutics. "India has a strong potential to become a hub for bio-pharma innovation and play a leading role in collaborative research for the same. "Now is the time for India to emerge as an innovator nation in the biopharmaceutical domain" Rosenblatt said. "Given their complementary strengths, India and the us have an unencumbered opportunity to partner in building a sustainable and affordable global healthcare paradigm. This summit is an ideal platform for catalysing collaborative innovation that can accelerate the delivery of affordable drugs to patients the world over," said Kiran Mazumdar-Shaw, CMD, Biocon and USAIC Advisory Board member. Among those participating in the day-long conference in Boston are Griffin Rodgers, director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of National Institutes of Health, Senior leadership top BioPharma companies- Merck & Co, Sanofi, Takeda, Janssen, Biogen, AstraZeneca, Boehringer Ingelheim, Merck KGaA.

3. **Why aren't you shopping for lower prescription drug prices?** – Economic Times

More than a dozen websites and apps are vying to help US consumers find the lowest prices for prescription drugs by comparing prices and searching for deals, similar to the way Expedia looks for cheap airfare or Bankrate.com looks for low mortgage rates. Patients who are taking

several generic drugs and have no insurance or high co-pays. Most of the largest savings to be had are for generic drugs, where competition between multiple manufacturers and pharmacies leads to a wide range of prices. Some of the priciest drugs won't appear on pharmacy apps at all. Specialty cancer drugs like Avastin, for example, must be administered at a doctor's office and aren't available at the pharmacy.

4. **US to establish lab network for combating 'superbugs'** – Business Standard
   US authorities have said they are establishing a network of labs that can respond quickly to antibiotic-resistant "superbugs", following America's first human case of a dangerous strain of E. Coli. State labs will be able to detect changes in antibiotic resistance and report the findings to federal authorities, leading to faster and more effective investigations and "stronger infection control among patients to prevent and combat future resistance threats." Its discovery in the United States for the first time "heralds the emergence of truly pan-drug resistant bacteria," said a Defense Department report on the finding published last week in Antimicrobial Agents and Chemotherapy, a journal of the American Society for Microbiology.

5. **Why academic trials are critical** – Financial Express
   Investigator initiated clinical research helps in finding cures to diseases that are widespread, but might not be the industry focus. The author, a professor and chief, thoracic surgery, Department of Surgical Oncology at Tata Memorial Hospital highlights how the industry has underestimated investigator initiated clinical research and its benefits for the patients. There are several examples of investigator initiated research products that do not require thousands of dollars in grant money and are easily implementable in India. Giving a scenario of the challenges faced by the clinical research fraternity, he says, several limitations still exist that either delay academic clinical research or curb its scope. While the approval processes in place are necessary from a safety perspective, we can expedite these processes while retaining the same level of precaution and safety. Indian Council of Medical Research said it would look at revisions in its guidelines to create a conducive environment for such trials.

6. **This 26-year old is building an OTC healthcare company to improve life quality of all Indians** – Yourstory.com
   The concept of an over-the-counter (OTC) healthcare company isn't new in the western world, where regulatory bodies have made it simple and streamlined for companies in the space. In India, this concept is just about picking up; Lifezen happens to be a startup in this space.

   According to a report by the Organisation of Pharmaceutical Producers of India: the term "OTC" has no legal recognition in India. All the drugs not included in the list of 'prescription-only drugs' are considered to be non-prescription drugs (or OTC drugs). Prescription-only drugs are those medicines that are listed in Schedules H and X of the Drug and Cosmetics Rules.

   In comparison to the Indian market, the European non-prescription medicines and OTC market is worth £29 billion at consumer prices and is said to be close to 36 percent of the world sales. In India, several bigger brands like Piramal Healthcare, Dabur, Dr. Reddy's and Mankind are tying up with various international brands to sell OTC drugs.

7. **Bit of a bumpy ride** – The Hindu
   A bilateral investment treaty between India and the U.S. looks difficult in the present circumstances unless either of the two sides blinks. There is a yawning gap between the two sides on core foreign investment protection standards, as reflected in their respective model BITs, which makes BIT negotiations really difficult. The Indian model completely excludes issuance of compulsory licenses (CLs) and revocation of intellectual property rights (IPR) from its purview. On the other hand, the U.S. model BIT excludes issuance of CLs and revocation of IPR only from the purview of the expropriation provision. In other words, while the foreign companies, including pharmaceutical companies, cannot challenge issuance of CLs and revocation of IPR as expropriation, they can surely challenge it as violation of other BIT provisions such as fair and equitable treatment (FET) — a pretty stretchable investment

protection provision that has often been abused by foreign corporations. Complete exclusion of issuance of CLs and revocation of IPR from the purview of the BIT might not be acceptable to the U.S. for two reasons: first, it would not allow U.S. companies to sue India directly for issuance of CLs or revocation of IPR; second, the U.S. continues to place India, along with China and Russia, on a 'priority watch list' for IPR violations, and thus would not like to foreclose opportunities for challenging India's IP laws internationally. India's recently unveiled IPR policy has cut no ice with the U.S

8. **Price cap, competition make heart medicines cheaper** – Hindustan Times
   The prices of drugs for cardiac ailments have come down by up to 54% in the past year, thanks to the government's price control initiative and intensified competition among drug makers. Along with competition, the government's decision to regulate prices led to around 100 cardiac ailment formulations seeing a dip prices. But that has not deterred companies from expanding their products portfolios. The cardio vascular (CVS) category, which contributes around 16% to the revenue of drug makers, is the largest therapeutic segment in India, with a market size of Rs 12,371 crore. The segment is growing at 13.3%, which is faster than the overall pharma industry. "We plan to introduce about three new drugs in cardiac category in next two to three years.

9. **Tweak the Make In India recipe** – Business Today
   A pet peeve of brand owners and manufacturers with large patent portfolios operating in India is that research and development (R&D) in the country largely happens only in public research institutions and universities. Indian firms don't invest in R&D and subsequently fill patents. A patent is a monopoly granted to its owner for 20 years in return for publicly disclosing an invention. Without the ability to enforce it, such a monopoly is not of much use. Patenting is also expensive and time-consuming, especially for an individual innovator without the backing of an employer that has the wherewithal for it. Many opt for filing patents via large companies while retaining their names as the inventors. The company thus owns the patent.

10. **DTAB approves health ministry's proposal for upward revision of fees charged for various licensing activities** – Pharmabiz.com
    The Drugs Technical Advisory Board (DTAB) has approved the Union health ministry's recent proposal to amend the Drugs and Cosmetics Rules, 1945 for upward revision of fees charged of various licensing activities under the Rules. However, the quantum of increase may be decided by the government in consultation with the stakeholders. The present fees were last upgraded in 2001 and 2003 only. The revision of fees was therefore considered necessary as the current fees were not upgraded since last thirteen years or so. Accordingly, the health ministry published the draft rules for comments from the public vide G.S.R. 1011 (E) dated 29.12.2015 without consultation of DTAB whereas the central government proposed to consult the DTAB within six months of from the date of publication of these rules.