1. **Health Ministry begins work on new law for safer drugs** - The Economic Times
   The laws governing the domestic pharmaceutical and medical devices industry will see a makeover by the Health Ministry. The Drugs and Cosmetics (D&C) Act and Rules will likely see revision in norms related to the examination of new drugs, systems and modes of drug delivery, a source close to the development said.

2. **Drug regulator finds Alkem Labs drug substandard, again** – Business Standard
   For the first time, the Central Drugs Standard Control Organisation (CDSCO) has found Alkem Labs' anti-diabetic drug Glimekem to be of substandard quality and has issued an alert for the drug. The regulator had issued alerts in June and July of 2015. The company was then asked by the regulator to recall the specific batches from the market.

3. **Mylan, Biocon upbeat on trial data involving breast cancer drug** – The Hindu Business Line
   At the ASCO 2016 annual meeting in Chicago, US drugmaker Mylan and Biocon have said that the recent trial data has further confirmed the efficacy and safety of their breast cancer drug MYL-1401O. This comes as a development that validates the quality of biosimilar drugs for cancer patients. MYL-1401O is a biosimilar product co-developed by the companies and it competes with the innovator Roche's branded Herceptin (trastuzumab).

4. **Bhupendra Singh, Chairman of NPPA, on affordable medicines** – The Hindu
   In an interview, Bhupendra Singh, Chairman of NPPA said that the government doctors will soon be expected to proscribe only generic drugs, as a step to ensure access to affordable medicines for the public. "The objective of the Indian government is to make the drugs on the National List of Essential Medicines (NLEM) as affordable as we can. In India, we do not have a system where the government insures or provides health care for everyone, like they do in United States. Till the time we evolve a system like that, we will have to cap prices on medicines. Job of NPPA is not to make medicines only 'affordable' but also 'available'," he said.

5. **The Rights of the terminally ill** – The Hindu
   In an opinion piece by Alok Prasanna Kumar and Dhvani Mehta on Euthanasia bill, the columnists state that the Bill does the bare minimum to give effect to the rights of competent terminally ill patients to refuse or request the withdrawal of life-sustaining treatment. This legal recognition of passive euthanasia has been a long time coming — the 196th Report of the Law

Commission of India made this recommendation as far back as 2006, and the Supreme Court gave effect to it in Aruna Ramchandra Shanbaug v. Union of India in 2011 — which makes the Bill's content more disappointing. The Bill virtually reproduces the model legislation set out in the 241st report of the Law Commission. The Commission had advised against recognising the legal validity of advance directives, and Clause 11 of the Bill regurgitates this recommendation without attempting to assess the merits of the Commission's objection.

6. **Will not just 'Make in India' but also 'Innovate in India' for the world: Dilip Shanghvi** - dna
Dilip Shanghvi, the promoter of Sun Pharmaceutical Industries, on Wednesday vowed not just to promote the campaign but will 'Innovate in India', thus pitching for Narendra Modi's 'Make in India' campaign in USA. "So Prime Minister sir, we promise you that as your 'Make in India' call to Indian industrialists and global citizens, we will not only make in India but we will innovate in India and take the products that we develop and make, to the world," he said after receiving 2016 US-India Business Council (USIBC) leadership award in Washington.

7. **US FDA approves Allergan's FDC Byvalson for hypertension & low BP** – Pharmabiz.com
Allergan plc, a leading global pharmaceutical company, announced the approval of Byvalson (nebivolol and valsartan) 5 mg/ 80 mg tablets, by the US Food and Drug Administration (FDA) for the treatment of hypertension to lower blood pressure. Byvalson is the first and only fixed-dose combination (FDC) of a beta blocker (BB) and angiotensin II receptor blocker (ARB) available in the US. "Achieving blood pressure control is critical to reducing the risk of serious and life-threatening cardiovascular events. There remains a need for new therapies, as observed by the nearly half of patients in the US who remain uncontrolled," said David Nicholson, chief R&D Officer at Allergan. "We are pleased with the FDA approval of Byvalson, which will provide physicians a new fixed dose combination therapy treatment option for patients affected by hypertension."

8. **IPR Policy falls short of policy integration and implementation strategy: Experts** – Pharmabiz.com
The new National Intellectual Property Rights (IPR) Policy unveiled by the Union government has fallen short of integrating Patent Act with Biodiversity Regulation Act to maximise its benefits for pharmaceutical industries and providing tax incentives for innovators to carry out research, according to patent experts. The IPR policy has no provision for designated courts for patent cases as well as implementation strategy, opined the experts. The experts addressing a panel discussion held by Organisation of Pharmaceutical Producers of India (OPPI) in Mumbai said the intention of the policy is noteworthy but it lacks a timeframe for implementation. The policy lays emphasize on need to prevent anti-competitive practices by taking action through the Competition Commission. It talks about the need for carrying out technology landscape studies to identify non-protected areas. However, these objectives would realize if the policy pushes for generation of IP without checking the quality of IP, said Komal Kalha, senior counsel (intellectual property), US Patent & Trademark office.

9. **Price control on stents not justified in patient's interest: experts** – Pharmabiz.com
Subsequent to Department of Pharmaceuticals (DoP) and Rajya Sabha Petitions Committee meetings on May 31 in Ooty and on June 2 in Bangalore to discuss pricing of cardiac stents, medical fraternity has opined that cost of stent is not the highest contributor to the procedure cost as the major burden of expenditure by patient comes from doctor fee, hospital stay, diagnosis, drugs, travel and stay. The DoP has also recommended to create a separate National List of Essential Medical Devices last year. In light of this proposal, adding medical devices into NLEM is a regressive step. According to experts, price control of medical devices will therefore reduce availability and choice for stents and will disrupt innovation.