1. **Govt weighs stricter norms, heavy fines in draft Drugs and Cosmetics Act – Mint**

The government is considering measures, including imposing heavy fines and imprisonment, in the draft Drugs and Cosmetics Act to prevent pharmaceutical companies from violating manufacturing norms, according to two health ministry officials. Consistent violations of the Good Manufacturing Practices (GMP) may invite not just suspension of drug licences, as is the case now, but also stiff fines and even imprisonment of executives.

Recalling batches of drugs that fail to conform to standards of strength, quality or purity is likely to be made mandatory after being notified by the drug regulator. Recalls are now made voluntarily or upon a directive being issued by the licensing or controlling authority.

2. **Bare-metal stents not inferior to costlier drug-eluting ones: Norwegian study – The Economic Times**

Contemporary bare metal stents are as good as drug eluting stents—their newer generation counterparts — a new Norwegian study on over 9,000 patients has found. The observation comes at a time when India has decided to clamp price controls on stents and the government is engaged with stakeholders in a raging debate over price categorisation between new and older stents.

The study, which looked at the long-term effects of the two classes of stents over a period of six years, found that patients with bare-metal stents did not have a significantly different quality of life from patients using drug-eluting stents.

At six years, the study recorded 16.6% rate of death from any cause and non-fatal spontaneous myocardial infarction in the group using drug-eluting stents, while the group using bare-metal stents recorded a 17.1% rate for the same.

3. **NPPA asks cos to ensure availability of Wilson's disease drug – The Times of India**

National drug pricing regulator NPPA has asked three pharma companies to ensure availability of Penicillamine, used for treatment of Wilson's disease, in the market. The drug is manufactured in India by three companies -- Panacea Biotec, VHB Life Sciences and Samarth Life sciences. "This office has been receiving complaints regarding shortage of Penicillamine drug (used for treatment of Wilson's disease) from different parts of the country for two months," National Pharmaceutical Pricing authority (NPPA) said. It has been brought to the notice of NPPA that due to shortage of raw material from China, the supply of Penicillamine has been affected, it added. "In this regard all the

three companies have been asked to ensure sufficient availability of the the said drug in the market," NPPA said.

Similar report-

- NPPA asks cos to ensure availability of Wilson's disease drug – The Financial Express

4. **Biocon gears up to launch new drugs to treat diabetes, cancer – Mint**
   Biocon Ltd will launch new branded formulations of its own and introduce products licensed from others to treat diabetes and cancer in the coming months, a top official at the bio-pharmaceutical firm said. The company will also approach more doctors through field staff and use digital technologies to train doctors and bring awareness among patients. "The immediate priority that we have is to expand our franchise for the offerings we have," Suresh Subramanian, head of branded formulations (India) business at Biocon said in an interview. Biocon is in talks with prospective partners for in-licensing novel molecules to strengthen its portfolio, Subramanian said. He did not name these companies.

5. **India To Review Drug Price Control To Make It More Lucrative For Pharma Companies: Report – The Huffington Post**
   In a move that could potentially result in higher prices of many essential drugs, the Indian government is considering a review of its current drug price control policy to encourage private investments in the sector. According to a report that cited a senior government official, Niti Aayog Chief Executive Officer Amitabh Kant has asked India's health ministry to scrap all regulatory hurdles for pharma companies. Niti Aayog sees the drug control regime as hindering investments in the sector, it added. The policy changing move, which is seeking to dilute the authority of the current drug price setting authorities, has backing from the Prime Minister's Office, according to the report.

6. **Zika vaccine race spurred by crisis and profit potential – Reuters.com**
   The race to find protection against the Zika virus is fueled by something often missing from tropical disease research: the potential for big profit. The prospect of a blockbuster vaccine against a mosquito-borne virus has accelerated the pace of development and attracted the interest of big drugmakers, including Sanofi SA (SASY.PA), GlaxoSmithKline Plc (GSK.L) and Takeda Pharmaceuticals (4502.T).
   Although Zika infections are mild or asymptomatic in most people, demand for a vaccine is expected to be strong because it can cause devastating birth defects, pharmaceutical executives and disease experts said.

7. **Pricing of Patented Drugs – Pharmabiz.com**
   Regulating prices of patented drugs is an issue long debated in the country with no indication of an immediate decision in sight. The Department of Pharmaceuticals (DoP) had set up an expert committee in 2013 consisting of members from the ministry of commerce, ministry of health, National Pharmaceutical Pricing Authority and also one from the DoP to look into the pricing of patented drugs in the country. The panel is yet to finalize its recommendations. DoP has been attempting to regulate prices of patented drugs after the amendment of the Patent Act since 2005. It came out with a draft policy on pricing of patented drugs in 2013 after consultations with all stakeholders. The draft policy was based on the report by the Committee on price negotiations for patented drugs appointed by the government eight years ago. This Committee was of the view that prices of patented medicines in the country are quite high considering the per capita income and purchasing power of the people. But, there was no action on the part of the government to implement the recommendations of this committee. Now, it is not clear how much time this new committee will take to submit its report and Department to act on it. Confederation of Indian Pharmaceutical Industry last month appealed to the government to come up with the pricing policy for patented drugs without any further delay.

8. **CDSCO to start online submission of drug samples by drug inspectors soon – Pharmabiz.com**
In a step further to digitise its services and usher in transparency in collection and analysis of drug samples, Central Drugs Standard Control Organisation (CDSCO) will soon start online submission of drug samples by drug inspectors for lab testing. The sample analysis report will be put online by the respective CDSCO laboratory. CDSCO has 7 laboratories including Central Drugs Laboratory (CDL) Kolkata, Central Drugs Testing laboratory(CDTL) Mumbai, Central Drugs Testing Laboratory (CDTL) Chennai, Tamil Nadu, Central Drugs Testing Laboratory (CDTL) Hyderabad, Regional Drugs Testing Laboratory (RDTL) Guwahati, Regional Drugs Testing Laboratory (RDTL) Chandigarh, Central Drug Laboratory, CRI Kasauli. Online submission of drug samples will be done via Sugam portal, developed by Center for Advanced Computing (CDAC). With an aim to check drug quality, currently CDSCO drug inspectors send drug samples for lab testing along with forms filled by them containing details of drug batch number, manufacturer, manufacturing and expiry date, molecules and formulations etc. They will now be allowed to submit online forms containing details of drug samples collected by them, said a senior CDSCO official.