1. **Government says no proposal to overhaul drug pricing policy – The Economic Times**

The National Pharmaceutical Pricing Authority (NPPA) may retain its independent powers to review and fix prices of drugs, the government has indicated. Speculations were rife a few weeks ago that NPPA's powers may be cut and decisions may be shifted to the Department of Pharmaceuticals under a proposal reportedly backed by the Prime Minister's Office.

There is neither a proposal to overhaul the drug pricing policy nor one to take away NPPA's powers, Mansukh L Mandaviya, minister of state for chemicals and fertilizers, told Parliament last week.

"There is no proposal at present to overhaul the drug pricing policy. However, minor changes are made in the DPCO (Drug Prices Control Order), 2013 from time to time to facilitate a smooth business environment and in the larger public interest," Mandaviya stated in response to questions on the country's drug pricing policy at the Lok Sabha on December 6.

2. **Spare a thought for Big Pharma – Mint**

Sometimes, just sometimes, it is possible to feel sorry for Big Pharma. One such moment came late last month when Eli Lilly and Co. announced that an Alzheimer's drug, solanezumab, which had been under development for years, had failed in a late-stage clinical trial. Eli Lilly has invested nearly $3 billion over the last 30 years in efforts to develop a drug for Alzheimer's, which causes progressive loss of memory and cognitive function. It has seven Alzheimer's medicines in various stages of development but sadly none so close to commercialization. Solanezumab failed in Phase 3 trials, which normally have an 80% chance of success.

The failure is a major setback in the fight against Alzheimer's not just in the US where it affects 5.4 million people, but also in the rest of the world, including India, which has over 3.7 million patients. With no known medicine capable of preventing or ameliorating the devastation caused by it, solanezumab was a great big hope all round. The pharma industry has already seen 15 straight failures on late-stage Alzheimer's trials.

3. **As drug approvals dive in 2016, returns on R&D deteriorate – Reuters.com**

The global pharmaceuticals industry is set to win the lowest annual number of new drug approvals this year since 2010 and a new report on Tuesday suggests drugmakers' returns on research investment are deteriorating. Only 19 new drugs have been approved in the key U.S. market so far in 2016 and, with less than three weeks to go, it is clear the full-year tally will be well down on 2015 and 2014's bumper haul of 45 and 41 new products respectively. At the same time the profitability

of drug research is being squeezed by steadily rising costs and increasing political pressure over the high prices of many modern medicines.

4. **India fares poorly on health indicators: WHO – Daily News and Analysis**

India is among the 194 countries that are aiming to attain Universal Health Coverage (UHC) by 2030 under the commitment to attain Sustainable Development Goals (SDGs). Going by the indicators released by the World Health Organisation (WHO) on their centralised portal to track progress towards UHC, India will have to strengthen its act. WHO has designed a Universal Health Coverage Profile for member countries entailing four parameters of assessment.

The first parameter is reproductive, maternal, newborn and child health. India records aboout three crore pregnancies every year. Only 45.5 per cent of all pregnant women get full ante-natal care with around four visits by the nurse. Even less, 19.7 per cent have access to doctors' services, according to data from the Health Ministry. India loses over 44,000 women to pregnancy-related complications every year, which means one woman dies every 12 minutes for want of care.

5. **USFDA finds lapses in testing methods, quality control at Sun Pharma's Halol unit – Mint**

The US Food and Drug Administration (USFDA) found lapses in testing methods, quality control processes and other standard operating procedures during an inspection of Sun Pharmaceutical Industries Ltd's Halol unit in Gujarat between 17 November and 1 December. On 8 December, Sun Pharma said in a stock exchange filing that the USFDA has made nine observations relating to violations of good manufacturing practices in its Form 483 issued to Halol plant following the inspection, but did not reveal details on the nature of the observations.

In a copy of the Form 483 seen by Mint, the US regulator says it has found inadequate testing methods, delay in submission of field alert reports for batches of buproprion HCl tablets, inappropriate stability data for drugs, inadequate laboratory control mechanism and laxity in adhering to standard operating procedures.

6. **THE FATE OF 344 FDCs – Pharmabiz.com**

Last week, the Delhi High Court reserved its verdict in over 450 petitions filed by drug companies challenging the notification issued by Drugs Controller General of India on March 10 this year banning manufacturing and marketing of 344 fixed dose combinations. The High Court had on March 14 stayed the DCGI ban order on appeals from several large and small pharmaceutical companies and was hearing the cases since then. The drug companies had contended that government did not properly implement the Section 26A of the Drugs & Cosmetics Act under which the ban was ordered. DCGI's stand has been that FDCs are "new drugs" and that makes it mandatory on the companies to conduct clinical trials and obtain marketing approvals from DCGI. But the fact is that most of these licenses were issued by State Licensing Authorities without conducting any clinical trials. A large number of these 344 combinations are cough syrups and other OTC products requiring no prescriptions. The list of these products also has combinations of drugs like nimesulide, cisapride and PPA which have been banned in many countries several years ago. Medical practitioners who rarely take note of periodical regulatory reviews of the authorities have been promoting these controversial products to their patients for several years.