1. **Indian drug firms to face challenges in US market: ICRA** – Economic Times

Indian pharma companies will face a number of challenges in the US market going ahead including reduced number of big products going off patent, increased competition and rise in regulatory scrutiny, ICRA said today.

Indian drug firms have registered strong growth over last decade driven mainly by the US market on account of large brands going off patent and sizeable organic and inorganic expansion.

2. **Pharma firms beware, CCI is inquiring** – Financial Express

The Competition Commission of India's (CCI) order dated February 10 imposing, for the first time, a penalty of R74.63 crore on a major pharmaceutical company (at a rate of only 3% of the average turnover, though it could have gone up to 10%) for refusing to appoint a stockiest in Kerala unless an NOC was obtained from the local Chemists and Druggist Association has come a shock for pharma manufacturers.

3. **Health ministry issues Guidelines on 'Similar Biologics' to lay down regulatory pathway for marketing authorisation in India** – Pharmabiz

The Union health ministry has issued Guidelines on 'Similar Biologic' which will lay down the regulatory pathway for a similar biologic claiming to be similar to an already authorised reference biologic. The guidelines address the regulatory pathway regarding manufacturing process and safety, efficacy and quality aspects for similar biologics.

A similar biologic product is that which is similar in terms of quality, safety and efficacy to an approved reference biological product based on comparability.

The Guidelines, prepared by Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT), also address the premarket regulatory requirements including comparability exercise for quality, preclinical and clinical studies and post market regulatory requirements for similar biologics.

4. **Drug ban: Inform states about relief to pharma companies, HC tells Centre** – Economic Times
   The Delhi High Court has asked the Centre to inform state governments about the interim relief provided to pharmaceutical companies petitioning the ban on their drug brands, said a lawyer present at the proceedings. The court has extended the stay on the ban until Wednesday while it hears the government's response to arguments laid out by Pfizer's counsel, said the lawyer.

5. **How can govt ban a drug without cancelling licence, asks HC** – Business Standard
   Delhi High Court today observed that power given under the Drugs and Cosmetics Act to prohibit their manufacture in public interest could only be regulatory in nature and asked how could the Centre invoke this provision without cancelling the licence given to manufacturers.

   "Section 26A (powers of central government to prohibit manufacture, etc., of drug and cosmetic in public interest) appears to be only a regulatory power as per the scheme of the Act. There is no other regulatory power.

6. **Patents dept to be renamed as Controller General of IPR** – Business Standard
   Government today said many steps, including hiring of more examiners, have been taken to reduce pendency of intellectual property applications, besides renaming the main office as 'Controller General of IPR'.

   All issues related to IP are handled by the office of the Controller General of Patents, Designs & Trade Marks (CGPDTM).

7. **'We're here to stay, open to buy right portfolio'** – Economic Times
   Mylan is committed to staying in India and r plans to build up its presence gradually while remaining open to acquisition if the right portfolio of products comes a long, says Rajiv Malik, president of the $11.8 billion Amsterdam-headquartered generic and specialty pharmaceuticals company. In an interview to Vikas Dandekar, Malik talks about Meda, the company Mylan acquired earlier this year for over $7 billion, and the arbitration procedure with Strides Arcolab over dispute of disclosures related to the Agila buyout.

8. **The changing pattern of healthcare in India** – Mint
   The evolution of healthcare in India over the past 25 years has been a mixed bag. While key health metrics such as the infant mortality rate (IMR) and maternal mortality ratio (MMR) have come down substantially, healthcare expenses have shot up—a direct fallout of lower public health spending. The government's allocation to healthcare as a percentage of the country's gross domestic product (GDP) has fallen to 1.05% in 2015-16 from 1.47% in 1986-87.

9. **India keen to re-engage with EU on stalled FTA talks: Nirmala** – Times of India
   Days after Prime Minister Narendra Modi's meeting with EU leaders in Belgium, India today said it is keen to sign the free trade pact with the 28-nation bloc at the earliest and will soon approach the authority for a meeting of chief negotiators.

   The statement came days after the two sides failed to made the much-awaited announcement on resumption of long stalled negotiations for a free trade agreement as many bottlenecks still remain.

10. **Makers took big price increases on widely used U.S. drugs** - Economic Times
    Major drug companies took hefty price increases in the U.S., in some cases more than doubling listed charges, for widely used medications over the past five years, a Reuters analysis of proprietary data found.

    Prices for four of the nation's top 10 drugs increased more than 100 percent since 2011, Reuters found. Six others went up more than 50 percent. Together, the price increases on drugs for arthritis, high cholesterol, asthma and other common problems added billions in costs for consumers, employers and government health programs.

Cabinet Secretary P K Sinha said that a number of decisions have been taken to reducing the time of patent application examinations.

11. **Pharma market to lose Rs 647 cr from drug price ceiling** – Business Standard
    After the National Pharmaceutical Pricing Authority fixed ceiling prices of 103 formulations last week, an immediate impact of Rs 647 crore (price to retailer) is estimated. The cardiac segment is the most hit, with a loss pegged at Rs 250 crore.

    Data analysed by AIOCD-AWACS, market research wing of the All India Organisation of Chemists and Druggists (AIOCD), representing about 500,000 medicine sellers across India, shows the coverage value of these 103 formulations is 4,839 crore or 5.3 per cent of the pharma market in the country.

12. **Healthcare and economic growth** – Mint
    It is no secret that health is instrumental to an individual's education, income and overall development. Studies show this is true for countries as well; health can be a causative factor for the aggregate economic growth of a country.

    The World Health Organization has estimated that a 10-year increase in average life expectancy at birth is associated with a rise in economic growth of some 0.3-0.4% a year. This evidence is available at the micro-disease level as well: for example, a 10% decrease in malaria is associated with an increased annual economic growth of 0.3%.

13. **Ranbaxy licence: Apex court notice to Centre** – Hindu Business Line
    The Supreme Court today directed the government to reply in two weeks on a plea seeking cancellation of licence issued to Ranbaxy Laboratories Ltd for allegedly selling substandard drugs in India.

    A Bench of Justices PC Ghose and Amitava Roy, which had earlier issued notice to the Health and Family Welfare Ministry on the plea, made it clear that no further time will be granted for filing its response.

    During the brief hearing, the petitioner advocate ML Sharma contended that the drug-maker was fined $500 million by the US Food and Drug Administration (USFDA) for allegedly making and selling adulterated drugs.

14. **India, Australia getting closer to a deal on FTA: Sitharaman** – Business Standard
    India has also demanded greater access in the services sector. "We have made our offers. But renewed and refined or enhanced offers are awaited. In services also, we are negotiating for a better offer from Australia having given our own wish-list," Sitharaman told reporters.

    Earlier, Finance Minister Arun Jaitley had said he expected substantial headway in negotiations for the agreement.