1. **SC agrees to hear Cipla over drug patent dispute with Roche** – Mint

The Supreme Court on Wednesday agreed to hear generic drug maker Cipla Ltd seeking appointment of an expert over a lung cancer drug patent dispute with Swiss innovator firm Hoffmann-La Roche.

In November last year, the Delhi high court had found Cipla guilty of infringing Roche's patent over lung cancer drug Erlotinib. Cipla's drug, Erlocip, was cheaper by at least one third as compared to that of Roche (being sold under the brand Tarceva), selling at Rs.1,600 a tablet, compared to the innovator's selling price of Rs.4,800 per tablet.

Also carried in The Financial Express

2. **Ethypharm receives patent for invention related to orally disintegrating pain killer, in India** – Business Standard

French pharmaceutical firm Ethypharm has received a favourable order for its patent application for granules and orally disintegrating tablets comprising pain killer Oxycodone as active ingredient, in India.

The Indian Patent Office has found the application in order for grant, as the company argued that its invention addressed a specific problem related to degradation of oxycodone in contact with an aminoalkyl methacrylate polymer.

3. **USFDA actions a key risk for Indian pharma companies: ICRA** – Mint

The increasing number of regulatory actions from the US Food and Drug Administration (USFDA) is emerging as a key risk for Indian pharmaceutical companies as it may delay product approvals and are likely to add to margin pressures, says a report by rating agency ICRA.

From 2008-2015, USFDA has issued around 50 warning letters on Indian companies. Out of these, around 40% were converted into import alerts. Sun Pharmaceutical Industries Ltd, Dr.Reddy's Laboratories Ltd, Cadila Healthcare Ltd and IPCA Laboratories Ltd were the major companies that faced USFDA heat in 2015.

Issuance of warning letters and import alerts for India-based manufacturing facilities have increased significantly over the past couple of years following USFDA's increasing focus on compliance of good manufacturing practices, the report says. It adds that one-third of warning letters issued between 2008 and 2013 have been resolved with majority of them belonging to large companies.

4. **Delhi HC extends stay on transfer of commercial IP right cases** – Mint

The Delhi high court on Wednesday extended a stay on the transfer of pending commercial intellectual property rights (IPR) cases up to the value of Rs.1 crore to district courts until 24 February.

"Suits relating to IPR, even below Rs.1 crore, should stay in high court. The suits which are filed in high court even when the pecuniary jurisdiction was Rs.20 lakh should not be transferred to district courts." Sudhir Chandra, counsel for Swiss pharma company Vifor International, had told the court on 3 December.

5. **Need more antibiotics, says expert** – The Hindu

With antibiotic-resistant bacterial infections rising globally, India is about ten years late in evolving a consensus on this vital issue as the State government sets the tone for an antibiotic policy, says Dr. Alison Holmes , Director, NIHR (National Institute for Health Research) Health Protection Unit on Anti-Microbial Resistance (AMR), England, and Professor of Infectious Diseases, Imperial College, London, and an expert on the European initiative called Transatlantic Taskforce on AMR.

In a conversation with The Hindu , Dr. Holmes said that the World Economic Forum at Davos had deliberated on the issue of de-linking the funding of pharmaceutical industry from the treatment and evolving a new model of providing incentive to innovations in antibiotic development. It is a challenge of the health industry where the pharmaceutical companies promote the use of antibiotics as well as the warning against too much exposure.

6. **US insurers dragging feet on covering new drugs, Novartis says** – Reuters

Getting U.S. government and commercial insurers to cover new medicines can now take longer than in Europe, Swiss drugmaker Novartis said on Wednesday, blaming U.S. delays for weaker than expected sales of a key heart failure treatment.

Last year, the U.S. Food and Drug Administration approved 45 novel drugs, the most since the all-time record of 53 in 1996.

However, Novartis said poor sales of one of those new drugs, its heart failure treatment Entresto - just $5 million for the fourth quarter, well off expectations of analysts as well as the company - resulted from delays in making new medicines available to insured patients.

7. **Massachusetts official challenges Gilead's hepatitis C drug prices** – Reuters

Massachusetts' attorney general is studying whether prices of Gilead Sciences' blockbuster treatments for hepatitis C violate state law, according to a letter the prosecutor sent to the California-based drugmaker.

The letter from the state's Attorney General Maura Healey to Gilead Chief Executive Officer John Martin, dated Jan. 22, asked the biotechnology company to reconsider its pricing for

Sovaldi and Harvoni, Gilead's treatments with list prices of $84,000 and $94,500, respectively, per course of treatment.

8. **Now, get drug license online within 30 days: FDA**[Now, get drug license online within 30 days: FDA] – The Times of India
Obtaining a license is set to get seamless and quick with the state Food and Drug Administration (FDA) making the process completely paperless. Applicants will no longer need to physically visit the office as every step — right from applying for the license, payment of fees to submission of documents — can be done online now.

The drug regulatory body has also made it mandatory for its officers to grant the licenses, wholesale as well as retail, within 30 days. Aimed at curbing red tape and corruption within the department, it is the first such initiative by any drug regulator in the country.

9. **RCEP agreement: Eye on 'essential pillars', meetings to be smaller and more focussed** – The Economic Times
The 16-member grouping of Asian nations looking to ink the Regional Comprehensive Economic Partnership (RCEP) agreement has decided on smaller and more focused meetings on the deal's "essential pillars." Officials said the next RCEP meeting, to be held in Brunei during February 15-19, will be smaller than previous rounds, with only a few subgroups on goods, services and investment.

RCEP is envisaged as a comprehensive free trade agreement subsuming goods, services, investment, competition, economic and technical cooperation, dispute settlement and intellectual property rights between the 10 countries under the Association of Southeast Asian Nations umbrella and their six free trade agreement partners - Australia, China, India, Japan, Korea and New Zealand.

10. **IICT to seek approval for clinical trials of two new drugs** – The Hindu Business Line
The Indian Institute of Chemical Technology (IICT) will be filing an investigative new drug application for two new molecules for treatment of cancer and Alzheimer's.

This was disclosed by IICT its director S Chandrasekhar on the sidelines of a felicitation function, held here on Wednesday, of former IICT director and founder-chairman of Avra Laboratories Pvt Ltd AV Ramarao, who has been honoured with Padma Bhushan (Science & Engineering).

11. **Big Pharma's bet on Big Data creates opportunities and risks** – The Economic Times
Novartis wants every puff of its emphysema drug Onbrez to go into the cloud. The Swiss drugmaker has teamed up with US technology firm Qualcomm to develop an internet-connected inhaler that can send information about how often it is used to remote computer servers known as the cloud. This kind of new medical technology is designed to allow patients to keep track of their drug usage on their smartphones or tablets and for their doctors to instantly access the data over the web to monitor their condition.

12. **Experts call for universal access to healthcare** – Pharmabiz
Experts have called for universal access to health care, substantial augmentation of human resources in the medical field, increasing access to drugs and vaccines, low-cost indigenous solutions and integration of alternative systems of medicine to enable India to overcome a number of serious challenges in realizing the right to health.

At the International Conference on Healthcare organised by O.P. Jindal Global University in collaboration with Harvard Global Health Institute and the Harvard T.H. Chan School of Public Health, several speakers emphasized that universal access to healthcare must be the focus of our efforts rather than universal health coverage through insurance.

"18 per cent rural population in the country has no access to healthcare," said Rakesh Kumar, joint secretary, ministry of health and family welfare at the inauguration of 'Delivering on the Promise of Universal Health Coverage in India: Policy Options and Challenges'.

13. **Editorial: Undermining innovation** – The Financial Express
Given the metrics of measuring countries' impact on global innovation, as per a new study by US-based think-tank Information Technology and Innovation Foundation (ITIF), include "innovation detractor" policies like low intellectual property rights protection and protectionist trade and investment norms, India, thanks to its export subsidisation, compulsory licensing, etc, stands an unsurprising third from the bottom in a ranking of 56 nations, together responsible for 90% of the world economy. It is, however, the contradictions evident in the indicators that the study deems "contributory" (policies) to enriching global innovation that the country's policy-makers need to take note of.