1. **India lags behind in leveraging intellectual property rights: CBEC Chief Najib Shah – Business Standard**

India is lagging behind in leveraging intellectual property rights (IPRs), Central Board of Excise and Customs (CBEC) Chairman Najib Shah today said and urged businesses to register their patent rights to fight against the menace of counterfeits and piracy. He also stressed on cooperation among key stakeholders for better enforcement of IPRs.

"India has been a little behind, perhaps,in leveraging in IPR and it has become an impediment," Shah said addressing an event on 'Illicit cross-border trade in goods: impact on economy and consumers' organised by industry body Ficci.

IPRs help to fight counterfeit and pirated trade, which has affected the entire economy and consumer welfare and safety, he said.

Emphasizing the need to create awareness about IPR, CBEC chief said, "We have repeatedly pointed out about the lack of enthusiasm in registering of IPRs by businesses. They need to take proactive steps. We have been encouraging. Unfortunately, the interest is very sporadic."

2. **Indian pharma industry facing growth headwinds: ICRA – The Economic Times**

Indian pharmaceutical industry will grow at a slower pace due to sluggish growth in the US market, increased competition leading to price erosion in high single digits and generic adoption reaching saturation levels, rating agency ICRA said today.

Growth from the US has come down to less than 9 per cent in first half of 2016-17 despite consolidation and currency benefits and going forward, the growth momentum is likely to face further pressure, it said.

Besides, increased regulatory scrutiny and consolidation of supply chain in the US market resulting in pricing pressure along with increased R&D expenses will have an impact on profitability of Indian

pharmaceutical companies, it added. "In spite of these ongoing challenges, several Indian pharma companies are increasing their R&D spend, targeting pipeline of specialty drugs, niche molecules and complex therapies," ICRA said.

3. **Get generic medicines dirt cheap by month-end – The Times of India**
The state government is to launch Jan Aushadhi Stores (JAS) in 254 locations across the state with an aim to provide generic drugs at affordable prices. The new scheme will strengthen supply of generic drugs in government-run health centres. Currently, the state government provides 241 medicines free. With opening of Jan Aushadhi Stores (JAS), number of drugs will go up to 649 medicines along with 161 surgical and consumable items. Drug and medical supplies will cost 40% to 400% less when bought from Jan Aushadhi stores. For instance, a strip of analgesics for pain and aches can cost as low as Rs 2.30 against a branded medicines, which cost 20 times more. "The state government is committed to processing the licences of applicants under the JAS scheme on priority," said principal secretary health Gauri Singh.

4. **'Expanding technology-enabled health care needs going beyond – Business Standard**
Expanding technology-enabled health care requires going beyond quick-fixes and working towards a sustainable health solution that can help tackle rising burden of communicable and non-communicable diseases in the country. This is the recommendation of a new report titled, 'Landscape of Technology-enabled Health care in India' by George Institute for Global Health. "While Digital India campaign being implemented by the government offers tremendous potential for strengthening health care delivery, accessibility and affordability, more robust evidence is required of what works and what does not in different community settings," Dr Vivekanand Jha, Executive Director, The George Institute for Global Health India said.

5. **Pharma shares tumble as Trump threatens to crackdown on drug prices – Business Standard**
Pharmaceutical and biotechnology shares tumbled early today after President-elect Donald Trump signaled that he plans to crack down on runaway drug prices. US stocks were mostly lower after Trump's comments, which followed controversies in recent months over massive drug price increases by Mylan, Valeant and other companies. "I'm going to bring down drug prices," Trump told Time magazine. "I don't like what has happened with drug prices." Time has named Trump its "Person of the Year." Dow member Pfizer dropped 2.4 per cent, Celgene fell 4.2 per cent and Mylan 4.7 per cent. The drug industry had initially rallied after Trump's election November 8 on expectations he would be less aggressive towards drug pricing than his Democratic rival Hillary Clinton.

6. **High prices today, effective drugs tomorrow – Mint**
Pharmaceutical investment is a particularly risky move, because it requires a huge amount of money to research and develop a new drug. And unlike most markets, there's a binary hurdle once you've finished developing the product: Either you get US Food and Drug Administration approval, or you don't. Most drug candidates don't pan out, and all that invested money is a complete write-off.

   America's high pharmaceutical prices are what compensate pharmaceutical firms for the risk of developing drugs. If we drive them lower, we'll get fewer new drugs. That makes for a hard trade-off: Higher prices drive up the cost of healthcare and mean that some folks may have trouble accessing the latest wonder drugs.

7. **NCD screening programme kick-starts in Jharkhand from Dhanbad – Hindustan Times**
The Centre's ambitious population based screening programme on non-communicable diseases (NCD) kick-started in Jharkhand from Dhanbad district. An orientation programme was organised at the auditorium of the civil surgeon's office in which state nodal officer of the programme Dr Lalit Ranjan Pathak, rolled out the project and informed medical officers, programme managers ,auxiliary

nurse mid-wives and healthcare workers how to implement it. The Centre has selected 100 districts across the country, including three in Jharkhand – Ranchi, Bokaro and Dhanbad–in the pilot project in which the population of the selected districts will be screened to detect non- communicable diseases like diabetes, hypertension, oral , breast and cervical cancers, said Pathak.

8. **The Delhi High Court allows 344 potentially dangerous combination drugs to remain in the market – Scroll.in**

On December 1, the Delhi High Court set aside the government's ban on hundreds of fixed dose combination medicines that included drugs often taken to treat colds and coughs like Corex, Vicks Action 500 and D'Cold. In his judgment, Justice Endlaw of the Delhi High Court quashed 344 statutory orders issued by the Ministry of Health & Family Welfare under Section 26A of the Drugs & Cosmetics Act. These statutory orders issued on March 10, 2016 prohibited the manufacture and sale of 344 fixed-dose-combination or FDC drugs.

As the name suggests, FDCs are combinations of existing drugs. The medical rationale for FDCs is to increase patient compliance where treatment of a disease requires patients to be treated with more than one drug. Instead of prescribing multiple tablets to the patient and risking the patient not consuming all of them as required, it makes sense to combine multiple drugs into a single medication – usually in the form of one tablet. The World Health Organisation has supported the development of FDCs in one of its reports, provided there is proof to substantiate the safety and efficacy of such combinations.

9. **Ensure affordable medicines – The Hans India**

The Union government's plans to overhaul the drug policy and ease regulatory framework may well be prescription of trouble for the common man. The change is going to impact access to affordable medicines, especially for the economically weaker sections and the lower income groups. The existing system of price control has been watered down, obviously due to pressure and lobbying from the pharmaceutical industry.

10. **Cipla gets USFDA nod for Hepatitis B treatment drug – Business Standard**

Drug firm Cipla today said it has received final approval from the American health regulator to market Entecavir tablets used for treatment of Hepatitis B infection. In a BSE filing, Cipla said "it has received final approval for its abbreviated new drug application (ANDA) for Entecavir tablets USP 0.5 mg and 1 mg from the United States Food and Drug Administration (USFDA)". The tablets are generic versions of Bristol-Myers Suibb's Baraclude tablets of the same strength, Cipla said.

11. **Ayush cos want govt to convince consumers of domestic, global markets about VCSMPP – Pharmabiz.com**

Drug manufacturers engaged in export of Ayush products want the union ministry of Ayush to make attempts to convince the consumers of domestic and international markets about the new certification scheme to be introduced by the National Medicinal Plant Board (NMPB) in association with the Quality Council of India (QCI).

In a letter to the Director of the NMPB, the EC member of the Ayurveda Drug Manufacturers Association (ADMA), said the NMPB's new initiative for implementing Voluntary Certification Scheme for Medicinal Plant Produces (VCSMPP) associating with Quality Council of India (QCI) is unlikely to succeed as the earlier initiative of the Board, Voluntary Certification Scheme for Ayush Standard and Premium Mark, had failed totally with no benefit for the Ayush drug manufacturers.

12. **Maha FDA sends license renewal request of 3 civic hospital blood banks to DCGI for approval – Pharmabiz.com**

Applications for renewal of licenses of civic run blood banks at KEM Hospital, Bhagwati Hospital, Borivali and Rajawadi Hospital, Ghatkopar have been sent to the Drug Controller General of India (DCGI) office for approval after Maharashtra Food and Drug Administration (FDA) inspections. This is followed by Maharashtra FDA directive to 306 blood banks in the state to submit applications of renewal of licenses by December 31, 2016.

There are 53 blood banks in the state for which renewals have been pending. Renewals for civic run blood banks LTMG Hospital, Sion and Bhabha Hospital, Bandra are currently in the process of being sent for further approval to the DCGI. The state FDA has taken up the task of renewal of pending licenses in an aggressive manner and has instructed the blood banks to complete their application modalities so that inspections can be carried out in a time -bound manner and approvals granted.

As per the Drugs and Cosmetics Rules, 1945, blood bank licenses are valid for five years. Central Licensing Approving Authority of Central Drugs Standard Control Organisation (CDSCO) renews licences after the state Food and Drug Administration (FDA) satisfies and recommends the same for renewal for further approval from the DCGI.