1. **Making India Effective** – Business World

Make in India was launched in 2014 with much fanfare by Prime Minister Narendra Modi to encourage local manufacture. The twin objects — to boost growth and provide employment — are laudable. However, with ever increasing challenges to guarantee manufacturers internationally recognised intellectual property rights (IPR), the rollout of the Make in India movement might just hit some major speed bumps.

Tabrez Ahmad, secretary general, Organisation of Pharmaceutical Producers of India, says the Indian pharmaceutical industry should move from being mere generic manufacturers to forward-looking, research-based companies. The Make in India vision cannot survive in the long term without concrete measures. "To increase patent protection to global standards, it is necessary that innovations arising out of dedicated R&D are protected through patents, designs, copyrights and other IPs so as to create certainty in the minds of innovators and increase investor confidence," says Ahmad.

2. **Interview: India's Growth Story** – Business World

Having driven many successful campaigns such as "Incredible India", Amitabh Kant, secretary in the Department of Industrial Policy & Promotion, is now the key driver of the "Make in India" initiative. we had said we would focus on innovation and design, and improve productivity in India. We have finalised the new intellectual property rights (IPR) policy. That should get approved shortly by the Cabinet.

3. **IPR policy will give industry the confidence to invest: Patrick Kilbride** – Business Standard

The latest edition of the US Chambers' International IP Index has been critical of India's IPR regime, ranking the country at the 37th place among the 38 economies surveyed. However, Patrick Kilbride, executive director of international intellectual property for the Global

Intellectual Property Center at the US Chamber of Commerce, tells Sudipto Dey that the impact of the proposed National IPR Policy - if implemented at the earliest - is likely to get reflected in next year's scores. Every moment lost is an opportunity cost. International industry is ready and waiting to make, invest, and innovate. The signals from government have been very positive. It's time to see the National IPR Policy and implementation of the rule that will give industry the confidence to invest in India's future.

4. **Govt may roll back customs duty hike on life-saving drugs** – The Hindustan Times
Faced with criticism over raising customs duty by up to 35%on some life-saving drugs, the government is now examining to roll back the move.

In a notification dated February 2, the Centre announced withdrawal of the exemption on customs duty on certain bulk drugs, including those used to treat parkinson's disease, heart failures, HIV and cancer. This will increase the duty by 5% to 35%.

The move caused a lot of furore, forcing the Prime Minister's Office (PMO) to intervene. Last week, the PMO held a meeting with top officials of the department of pharmaceuticals (DoP), revenue and health ministry, to review the decision of doing away with the exemptions.

Pharma companies are also disappointed by the move.

"We were not consulted at all. The decision needs to be re-visited," said Ranjana Smetacek, director-general, Organisation of Pharmaceutical Producers of India, the biggest lobby representing foreign drug firms in India.

5. **Ranbaxy Whistle Blower may Bat for Drug Quality in India** – The Economic Times
Dinesh Thakur, who rattled the generic drug industry in India through his expose of malpractices in Ranbaxy as a whistle blower, may be looking to address issues related to the quality of pharmaceutical products in the country. He's considering setting up a patient advocacy group that will aim to increase transparency and accountability among drug makers in India, according to people aware of the matter.

Thakur is said to have approached public relations companies in India to initiate the campaign that will try to raise matters related to drug safety standards. Thakur, however, denied any such plans in an email to ET. However, others said Thakur has shared his ideas with a few people on how the process could be taken forward. Such a move, if it does come about, would take place as top Indian drug makers face USFDA strictures over non-compliance with quality standards. Since November 2015, the USFDA has issued warning letters to leading Indian drugmakers Sun, Dr Reddy's and Cadila for not complying with good manufacturing practices.

6. **Ministry matters** – The Hindu Business Line
For a country which is a major global player in the global pharmaceuticals sector and whose prowess in generic formulations is feared by the world's pharmaceuticals behemoths, it may come as a surprise to many that India doesn't have a full-fledged ministry for pharmaceuticals. Very few countries around the world actually possess such a ministry, but it is pretty astonishing in India where we have a ministry for practically every letter of the alphabet. That's why the industry was relieved when the Modi government announced that it plans to finally free the department of pharmaceuticals from the overarching control of the ministry of chemicals and fertilisers (itself an odd combination — fertilisers are chemicals, but a far cry from the industrial chemicals the ministry is actually concerned with).

The industry is pleased, but is not readying to celebrate as yet, since the issue has not officially progressed beyond a statement by Fertiliser Minister Ananth Kumar at an industry conference in December, where he was quoted as saying that a separate pharmaceuticals and medical devices ministry would take shape by the end of calendar 2016.

7. **Modi: No retro taxes, more reforms in the offing** – Bloomberg TV
   Ahead of the Budget, Prime Minister Narendra Modi on Saturday promised that the government will not come up with any retro taxes even as a series of reforms are in the offing including ease of doing business, a new IPR Policy and patent regime, and a bankruptcy law. "Soon we shall be putting in place an effective IPR Policy and patent regime. We hope to pass the Bankruptcy law which has been tabled in Parliament," he said.

8. **Glaxo fined $54.4 million in UK probe of 'pay-for-delay' deals** – Mint
   GlaxoSmithKline Plc was fined £37.6 million ($54.4 million) by the UK's antitrust watchdog over pay-for-delay deals that held back sales of cheaper generic versions of anti-depressant drug paroxetine.

   The Competition and Markets Authority said the London-based drugmaker colluded with other companies from 2001 to 2004 by agreeing to make payments "and other value transfers totaling over £50 million to suppliers of generic versions of paroxetine," according to a statement on Friday. The agreements blocked generic drug companies from entering the UK market.

9. **Eli Lilly loses latest round in UK drug patent battle** – Reuters
   Eli Lilly said on Friday it lost the latest round of a lengthy patent saga over its blockbuster Alimta lung cancer drug in the UK High Court, in a boost for generic drugmaker Actavis, now renamed Allergan.

   Alimta, known generically as pemetrexed, had worldwide sales of $2.49 billion last year, making it Lilly's second biggest-selling product.

   The setback follows a win for Lilly in the UK appeals court in June and highlights the complexity of legal arguments over patents that cover the administration of vitamins given alongside Alimta.

10. **Keen to use India's brain power, says Paul Stoffels, Chief Scientific Officer, Johnson & Johnson** – The Economic Times
    Dr Paul Stoffels, chief scientific officer at Johnson & Johnson, is most recognised in the global drug industry for his contributions in bringing to market a broad range of latest generation anti-HIV drugs. Stoffels, who is also the worldwide chairman of the US drug major's pharmaceuticals group, was in India recently to take stock of his company's operations. In an interview with ET, he talked about J&J's interest in doing more in India and how its clinical development programme in the country is back on track after it was scaled back for a couple of years.

    The issue of antimicrobial resistance has come because of the excessive use of antibiotics. In uncontrolled or partial regimens that builds resistance, the antibiotics will fail. Few things need to happen like faster and simpler diagnostics and then getting to new targets.

11. **UK-India call for wider use of vaccines** – Deccan Chronicle
    A recent study by British Economist Lord Jim O'Neil, Chairman of the Review on Anti Microbial Resistance (AMR) has come up with path breaking recommendations which challenge the prevalent practices on drug resistance.

    The 6th report on the Review on Anti Microbial Resistance was published on February 11 that sets out that there are too few vaccines and alternative approaches to antibiotics available for doctors to use to tackle many of our most urgent drug resistance threats. More investment needs to go into developing these products.

12. **No Method in the Madness** – Economic and Political Weekly
    The decision to impose a customs duty of 22% on a list of 76 life-saving medicines is symptomatic of several things wrong with the pharma pricing scenario in India. One arm of the

government, the Department of Pharmaceuticals, is in charge of implementing the Drugs (Prices Control) Order (DPCO) 2013. Another arm, the Ministry of Health, is nowhere as they are seen as probably not relevant to the issue. The DPCO-2013 has put 348 medicines of the NLEM-2011 (National List of Essential Medicines) in specific formulations and specific strengths, and only those, under a price ceiling. The calculation of the ceiling price itself is flawed based on a naïve simple average market-based price mechanism. This legitimises the already high drug formulation prices. The flawed DPCO-2013 nevertheless succeeds in putting a brake on prices of some essential medicines, even if it covers only a maximum of 15% of the domestic pharma market of around Rs 90,000 crore. The list of 76 drugs, on which customs duties are now to be imposed, has those in common with the 348 drugs of the DPCO-2013 and the recent NLEM-2015. So why does the government giveth to the patient with one hand and taketh with the other? Because the many arms of the government are not in conversation with each other.

13. **CBI registers case against NIPER officials** – PTI
A case of alleged corruption has been registered by CBI against officials of National Institute of Pharmaceutical Education and Research (NIPER) and a private company in the purchase of licenses for accessing a global patent database software causing losses of Rs 10 crore.

CBI sources today said eight officials of the Mohali-based autonomous Institute under Ministry of Chemicals and Fertilisers including present officiating Director, former Director and other senior officials have been named by the agency in the agency FIR.

They said a Pune-based private company Sciedge Informatics has also been named in the FIR filed under IPC sections relating to criminal conspiracy, cheating, forgery and provisions of Prevention of Corruption Act.

It is alleged that the company was supplying annual licenses for accessing global patent database software 'Scifinder' at the rate of 36,000 USD to other companies while it was supplying these licenses to NIPER at the rate of USD 51,000 annual rate thus causing a loss of Rs 10 crore between 2007 and 2012, the sources said.

14. **Spluttering against TB** – The Hindu
India has close to 1,00,000 cases of drug-resistant TB, most of which remain undiagnosed and untreated. So India's state of preparedness to fight DR TB remains questionable. Most patients cannot access accurate diagnosis or affordable forms of treatment due to systemic barriers, stigma and affordability. Afraid that the public system will not deliver, over half of them seek care in the private sector. Over the years, by benign neglect and inefficiencies, the government has designated the private sector as the primary provider of TB care.

Recently the government announced that it would be introducing 500 rapid machines to diagnose TB and drug-resistant TB, significantly enhancing India's ability to diagnose DR TB. There was a similar announcement about the use of Bedaquiline, the new promising drug for DR TB saying that India would receive 600 courses in the form of a donation from its manufacturer Janssen. Despite all this, many ask whether this is enough considering India's growing crisis of drug resistance.

15. **Pharmaceutical drugs: call for uniform regulatory standards** – The Hindu
A senior official of the US Food and Drug Administration has underscored the need for uniform regulatory standards for pharmaceutical drugs.

Participating in a panel discussion conducted as part of the 10th anniversary of US Pharmacopeial Convention (USP) laboratories and offices in Hyderabad, USFDA Director-India Mathew Thomas said there should be same standards of drug quality for everyone. Such a move would sustain the pharmaceutical industry as well as the regulatory agencies.

16. **Clinical trials weapon of last resort in cancer battle** – The Hindu
    Doctors say clinical trials still come across as a risky proposition to many who think they will be used as guinea pigs and subjected to the unknown. Unscrupulous trials have added to the fear. “It is a very minor group of people who come and ask for trials, but that minor group has marginally increased,” said Dr Almel, adding that those who can afford it have also enrolled in clinical trials in cancer centres abroad. The drug given during the trial is free, but the registration fee with premier medical facilities runs into thousands of dollars.

    Even in cases when new drugs are launched, they are prohibitively priced. Dr Pramesh, in his speech at the annual conference of the Indian Society for Clinical Research held recently, pointed out the limited efficacy of new drugs, their high cost and the need for investigator-led clinical research. But more importantly, he said that while the clinical research industry was focused on cancers of the lung, prostate and colorectal area, and melanoma, the more prevalent cancers in India were those of the head and neck, breast, cervical and gall bladder.

17. **Sun Pharma ends tie up with MSD** – The Times of India
    Sun Pharma's revenue grew marginally by 2% to Rs 7,047 crore for the third quarter ended December 2015, impacted primarily due to lower sales in the US, and supply constraints at its key plant, Halol, closed post the US Food and Drug Administration warning. The company's net profit reduced to Rs 1,417 crore for the quarter, as against Rs 1,425 for the corresponding period previous year. The Sun Pharma scrip gained marginally by 2% to close at Rs 848 on the BSE on Friday. The company announced it has ended its collaboration with MSD to develop and commercialize novel formulations and combinations of medicines for emerging markets, due to changes in priorities. Sun Pharma said it would not be materially impacted by the termination of the agreement, struck with New Jersey-based Merck in 2011.