1. **India's IPR regime is robust – almost** – Economic Times Blog

   The editorial on ET blog puts forth three caveats on the recently announced IPR Policy. Section 3(d) of the Indian patents law is wildly disliked by global pharma giants, even if its refusal to distinguish between different forms of the same molecule for the purpose patents unless the different forms have demonstrably different therapeutic efficacy is conceptually sound and compliant with the World Trade Organisation's Trade-Related Intellectual Property Rights Agreement. India needs to evangelise its merits among other countries to garner support against rich-country resistance to it. Second caveat is about the working of the compulsory licensing regime. Only when the price-controlled drug ceases to be available should compulsory licensing kick in. A final caveat is that merely having a good IPR regime will not produce innovation and creativity.

2. **How drug whistle-blowers in India have to fight a long battle** – Economic Times

   The article highlights the act of whistle blowers who have raised voice against company malpractices in the healthcare sector. Highlights cases of Dinesh Thakur (Ex-employee Ranbaxy Labs), Sanjiv Chaturvedi (Chief Vigilant Officer – All India Institute of Medical Sciences), Narayan Konduru Reddy (Ex-employee GVK Reddy). Even big Indian companies have not been able to meet FDA's quality standards. In the last two years, companies like Sun Pharma, Dr Reddy's and Cadila have all faced FDA's heat for not meeting good manufacturing practices. It reflects on the long struggle that the whistle blowers have to face and the challenge of receiving no recognition for their efforts in India. In India his efforts have not even been acknowledged, according to Dinesh Thakur. Thakur has turned his attention to drugs produced and consumed by Indian citizens, but has hardly been able to make a dent.

3. **Troikaa may take govt to court over Novartis' Drug** – Economic Times

   Gujarat-based Troikaa Pharma plans to drag the government to court for not putting a stop to sales of multinational drug maker Novartis' India's popular pain killer injection. The company claims that the painkiller marketed by Novartis contains an ingredient that could compromise patient safety, as it is not used in injections anywhere else in the world. The government may have now found itself caught in the midst of a battle between the pharma companies. Novertis'

Voveran 1ml is one of two brands of the Diclofenac Sodium painkiller injection produced by Indian drug company Themis Medicare, the other bring Themis' own brand – Aquadol.

4. **Meeting halfway** – Business Standard
   Going by their initial reactions, many of the pharmaceutical companies and other intellectual property stakeholders do not seem to be fully satisfied with the policy, though they have welcomed the stress laid on better administration and enforcement. The two reasons for discontent that stands out: The first relates to the provision for compulsory licensing for local production of unaffordable pharmaceutical products to meet health emergencies and serve the national interests. The second is the strict definition of patentability in clause 3(d) of the amended Indian patent law that disallows evergreening of patents on grounds such as "insignificant" incremental innovation or minor tweaking of the formula. India argues that these are fully compliant with the TRIPs agreement.

5. **Ease of doing business needs to improve: US Official** – Business Standard
   According to a study by World Bank last year, Gujarat, Andhra Pradesh, and Jharkhand topped the list of states. India needs to improve its ease of doing business, which continues to lag behind that of G20 (Group Of Twenty, a group of finance ministers and central bank governors from 19 of the world's largest economies, and the European Union) to attract foreign businesses to invest in the country, Arun M Kumar, director-general of the US (United States) and Foreign Commercial Service, said on Wednesday. Trade between the countries would have to take into account the realities of the Trans Pacific Partnership, the mega trade deal between pacific nations like Japan, Austalia, Canada and the United States, among others. On the Intellectual Property Rights (IPR) policy recently released by the government, Kumar said centralizing the copyright and patent regimes under DIPP and improving co-ordination between the Centre and states on compliance have been a welcome move.

6. **Govt approves three pharma FDI proposals worth Rs. 60.73 crore** – Hindu Business Line
   The Government has approved three foreign direct investment proposals, all related to the pharmaceutical sector, worth Rs. 60.73 crore. Axis Bank's FDI proposal worth Rs. 12,973.14 crore to increase foreign investment by FIIs / NRIs/ FPIs / ADRs / GDRs from 62 per cent to 74 per cent has been referred to the Cabinet Committee on Economic Affairs (CCEA). This is in line with the government's decision to refer all FDI proposals above Rs. 5,000 crore to the CCEA. The highest FDI proposal of the three pharmaceutical companies which got the nod was from Advanced Enzyme Technologies. The company sought approval for investment proposed to be made by FIIs / NRIs / FPIs / QFIs / AIF/FVCIs pursuant to fresh issue of and offer for sale of 44,73,470 equity shares by certain NRIs and resident shareholders worth Rs. 60 crore.

7. **Experts warn against misuse of antibiotics** – Times of India
   Health experts have warned the public not to go for self-medication when it comes to the use of antibiotics. The inappropriate use without the prescription of doctors will lead to drug resistance in the body, which is considered as one of the cause of deaths worldwide, according to experts. The government has urged pharma companies to create awareness among public to curb its misuse on the basis of a concern expressed by the World Health Organisation (WHO) about the possible complications due to antimicrobial resistance. According to the WHO, antimicrobial resistance is expected to result in around 10 million deaths across the world by 2050. At present, many consumers have been consuming the antibiotics without the proper prescription of the doctors and guidance.

8. **Anti-rejection drug prices cut by 65%** – Times of India
   In a huge respite for such patients, the National Pharmaceutical Pricing Authority (NPPA) has reduced the rates of these drugs, with the cost of most-widely used Tacrolimus being slashed by 60-65%. For a patient in need of an organ transplant, finding the right donor and undergoing the procedure is just half the battle won. Thereafter, living with the foreign organ comes with a huge price tag in way of immuno suppressants or anti-rejection drugs which the recipient has to depend on for the rest of his life.

9. **Hasten patenting to get IPR policy** – Deccan Herald
   Opinion piece in Deccan Herald on IPR Policy: On the face of it, the national Intellectual Property Rights (IPR) policy looks great as it seeks to promote and reward innovation through an efficient and easily accessible IPR regime. Some of the objectives set forth in the policy cleared by the Union Cabinet are quite laudable. These include creating awareness, in the first place, about the IPR itself because majority of our people would not even know what the intellectual property rights are. This is so because bulk of our economy is driven by the informal sectors which too can participate in the innovation drive of a progressive nation. While it is true that the universities and scientific institutions along with well-funded research and development units of the corporate firms have to be at the vanguard of the IPR-driven discoveries, the product development can take place even by small time artisans making farm equipment or a service provider coming out with a unique concept. No doubt, there has to be a dispensation to cater to the needs of all these segments in terms of processing, approval and grant of patents which can also be monetised. The multilateral and the bilateral trade negotiators, always complaining about Indians not respecting patents and IPRs, should take a look at this pendency which shows how enthusiastic the innovators and businesses are about owning up their creations, only to be kept waiting. Hopefully, the new policy would address this big concern. Although the government does have a right to resort to compulsory licensing if undue advantage is taken by a monopoly thriving on its patents under the WTO-TRIPS agreement, at the popular and mass level we cannot have a situation where the police have power to wield its stick in an area totally alien to it. That will surely be counter productive. Besides, a balance must be struck to ensure that the free flow of knowledge is not impaired at the altar of IPRs.

10. **'Budget for health will not be a problem… only, you have to spend, says JP Nadda** – Indian Express
    A Q&A with J P Nadda: Health Minister J P Nadda tells Abantika Ghosh that while rural health services have to be strengthened, the Centre is not getting the required response from state governments. The Prime Minister is sensitive towards health (sector) and it is being given top priority. Last year, for the first time, real expenditure exceeded budget estimates. This year there is a 39-per cent increase. The capacity of expenditure — we showed 96 per cent capacity…by our hard work involving the states… Budget will not be a problem in the coming days as well — only, you have to spend. On completion of 18 months, a thought on what could not be achieved. Rural health services have to be strengthened — that is one area where I am not getting the kind of response from the states that is needed. The problem is you have to take strong political decisions on rural postings. We have done all that could have been done from our side. We have given full powers to all state governments — come out with your own legislations if you have to, we do not mind.

11. **New Indian IPR policy to establish an ecosystem that is conducive to foster innovation and creativity** – Pharmabiz.com
    Origiin IP Solutions LLP sees the National IPR Policy of India to establish an ecosystem in the country that is conducive to foster innovation and creativity not only in terms of IP creation but also commercialization and enforcement. Specific to the pharma, it prohibits grant of patent for new form of the same substance till improved efficacy is established. There has been clear emphasis on protection, exploitation and enforcement of IP but at the same time, attempt has been made in order to protect public health, food security and environment, among other areas of socio-economic importance. This policy is expected to create an environment in the country where awareness of IP is established across R&D organizations, educational institutions, corporate entities including startups, and micro, small and medium enterprises, Bindu Sharma, patent attorney and chief executive officer, Origiin IP Solutions LLP, Bengaluru told Pharmabiz.

12. **Good Pharmacovigilance practices** – Pharmabiz.com
    Editorial on the topic: Pharmacovigilance programme started in India with the formation of a National Pharmacovigilance Advisory Committee in 2004 under the chairmanship of the then Director General of Health Services with the intention of building a comprehensive ADR data bank for drugs marketed in the country. The progress of the countrywide collection of ADR data

has been rather slow in the initial years of the programme with inadequate number of monitoring centres. However, after Indian Pharmacopoeia Commission took over as the National Coordination Centre for the programme in 2010 the ADR data collection improved somewhat better. For collection and compilation of reliable ADR data across the country there needs to be a network of medical colleges or hospitals. IPC now claims to have 179 adverse drug reaction monitoring centres (AMCs) in different parts of the country and it plans to take the number to 200 by end of this year. IPC also received over 100 applications expressing intent to associate with it for ADR reporting. Such responses from stakeholders indicate that the programme seems to have well received by all the stakeholders considering the huge number of new drugs and irrational combinations in the domestic market.

13. **Pharmaxcil to form expert forum to provide guidance on implementation of track and trace rule** – Pharmabiz.com

    The Pharmaceuticals Export Promotion Council of India (Pharmexcil) will soon form an expert forum to provide guidance to the exporters on the implementation of track and trace rule. The forum will consist of representatives from GS1, National Informatics Centre (NIC), Industry, Pharmexcil and some vendors will also be part of the forum. The issues faced by the exporters over the implementation of track and trace rule will be addressed and will also be shared with the other members. After being authorized to examine the exemption applications on barcoding, the Council is also planning to come up with the online programme which will help the companies to submit their applications online so that it reduces the time of the exporters.