1. **Health ministry invites views on easing the drug regulation process** – Economic Times
The health ministry has invited pharmaceutical and medical device associations to share their views on easing the drug regulation process in the country. At the same time, some associations have criticised the move, stating that the ministry is yet to act to on the input already provided to improve the business climate for the country. "The Ministry of Health and Family Welfare is currently examining the ways and means of facilitating ease of doing business with regard to various approvals/clearances in respect of drugs and cosmetics and related areas," the ministry stated in a notice dated May 6. The story includes quotes from Indian Pharmaceutical Alliance, AdvaMed and AIMED. The ambiguity between regulated and unregulated medical devices has also led to confusion and "grey areas" between state regulators, according to Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AIMED).

2. **Roche moves court to block copies of cancer drug Avastin, A La Herceptin** – Economic Times
Roche has challenged the regulator and pleaded to block the approvals of the drugs under review, et learned from highly placed legal sources. The case was heard on Monday and is deferred till Friday. Avastin raked in close to $7 billion in global sales for the company. In an interim ruling delivered last month, the Delhi High Court sided with Roche but at the same time allowed the Indian companies to market their respective products on the condition of certain changes to the labelling and packaging of their products. Roche's decision to litigate further on copies of Avastin is seen as a pre-emptive strike to prevent competition. The committee reviewed the Phase III clinical studies presented by Intas for bevacizumab in metastatic or recurrent non-small cell lung cancer and concluded that its efficacy was similar between the test arm and the reference arm. The Swiss drug maker had been under attack from health activists who saw the company's stand as a tactical game plan to block competition from low cost variants. Roche on the other hand maintained its challenges are to ensure the safety of the patients.

3. **US drugmaker Bristol Myers Squibb out of Biocon's oral insulin project** – Economic Times
   Bengaluru-based Biocon will have to develop oral forms of insulin on its own as US drugmaker Bristol Myers Squibb , its global partner for the project, has "not exercised the option". Sector experts, however, said Biocon will continue to look for other partners. In 2012, Biocon and BMS had signed an agreement to jointly develop oral forms of insulin - an ambitious project spearheaded by the Indian biotech company. BMS confirmed the decision to ET . The move, however, does not come as a surprise. Even while BMS was undergoing the shift, it had retained Biocon's alliance for the oral insulin compound. BMS had then mentioned of an exclusive "option agreement" deal with Biocon to develop and commercialise the oral insulin drug (later named Tregopil), pending outcome of clinical trials. Under the terms, BMS had the right to exercise an option to obtain an exclusive worldwide licence to the product.

4. **Need to speed up process of granting patents: Wockhardt Chairman Habil Khorakiwala** – Economic Times
   India needs to fast-track patent and trademark approval mechanism as the time taken for the same in the country is much higher compared to other nations but the Centre's National Intellectual Property Rights policy is a welcome step. The recently launched National Intellectual Property Rights (IPR) policy is a step in the right direction and towards creating an ecosystem for innovation, and it also brings clarity on India's position on IPR framework, he said, adding that a "not so friendly" clinical research environment prevails in the country. "Weightage should be given to a product patents as compared to a process patent application. There should be a fast track system to clear such patents," Khorakiwala said. He added that there is a problem of delay in granting trademark approvals as well.

5. **Govt plans strict enforcement of copyright law to tackle piracy** – Mint
   There is complete absence of enforcement of copyright though there is a law, says commerce minister Nirmala Sitharaman. Makers of pirated products in India face the prospects of a crackdown, with the government planning strict enforcement of the copyright law under its new intellectual property right (IPR) policy. The Centre is also planning to form an IP cell in the department of industrial policy and promotion (DIPP) to coordinate with state governments and train and sensitize them to counter copyright infringements of books, music and movies among other products. "We will also encourage industry bodies and book publishers to conduct roadshows all across the country, sensitizing general public against falling for pirated products," Sitharaman said. The new IPR policy seeks to put in place a legal framework that will encourage the IPR regime and reduce the time taken by the government to approve a trademark to a month by 2017. Currently, the process takes more than a year.

6. **India to train drug manufacturing units in good practices to address USFDA's concerns** – Mint
   CDSCO officials will visit drug manufacturing hubs of the country over the next three to four years and train employees in producing quality medicines. "It is high time that we put proper practices and regulation in place for the pharma industry. India has one of the biggest generic industries in the world, and we need to ensure quality of medicines produced here," said G.N. Singh, Drugs Controller General of India, who heads CDSCO. CDSCO has hired 500 personnel to set the ball rolling, he said while speaking to *Mint*. Employees trained by CDSCO will be expected to further train employees of other units. Drug manufacturing is regulated by respective states in India, which show major variance in regulation. USFDA inspectors have questioned the processes followed by several Indian manufacturers. Another issue that has caused concern among international agencies like the World Health Organization (WHO) is improper maintenance of records of production and testing. The Indian move follows the commerce ministry announcing last month that the government is considering setting up specified pharmaceutical zones to boost domestic manufacture of active pharmaceutical ingredients. It will reduce the country's dependence on China for the raw material used to produce drugs, especially antibiotics.

7. **China's Fosun bids to buy India's Gland Pharma** – Mint
   KKR, which owns a significant minority stake in Gland Pharma, would see its second private equity exit in India in 2016 if the deal materializes. Shanghai Fosun Pharmaceutical (Group) Co. Ltd, the Hong Kong-listed company controlled by billionaire Guo Guangchang, said it had submitted a non-binding proposal to acquire a 96% stake in India's Gland Pharma Ltd. Fosun's bid for a controlling stake in Gland Pharma is a rare instance of a Chinese drug maker seeking to buy an Indian company. Foreign investments from China have long been viewed with suspicion in India. US pharma major Baxter International Inc. has emerged the front-runner to buy Gland Pharma for over $1 billion, The Economic Times reported on Thursday. Advent International, Baxter and Torrent Pharmaceuticals Ltd are among contenders for Gland Pharma, Reuters reported last month. Several Indian injectable makers have attracted interest from foreign buyers. In 2013, Bengaluru-based Strides Arcolab Ltd sold Agila Specialties, its injectable drugs unit, to US-based Mylan Inc. for a total consideration of $1.75 billion. The global market for injectables was estimated to be around $300 billion in 2014. The US accounts for around 35% of the market. The Indian market is estimated to be around $2 billion.

8. **Pfizer to buy Anacor in $5.2 bn deal** – Business Standard
   Pfizer Inc is buying Anacor Pharmaceuticals Inc in a $5.2-billion (£3.61 billion) deal to add an eczema gel to its portfolio, just a month after the US drug major scrapped plans to acquire Allergan Plc.
   Anacor shares surged more than 55 per cent to $99.48 in late morning trading on Monday, above the offer price of $99.25 per share in cash. The net-of-cash deal value assumes conversion of Anacor's outstanding convertible notes, the companies said in a statement. Pfizer's current inflammation and immunology drugs portfolio includes Enbrel and Xeljanz, which target auto-immune diseases. Enbrel, marketed by the company outside North America, lost patent protection in Europe last year. The U.S. patents for the drug, sold in the country by Amgen Inc (AMGN.O), are set to expire in 2028.

9. **The curious case of generic Hep C drug Sofosbuvir** – The Hindu Business Line
   An authored article by Leena Meghnany from MSF. In her write up she highlights patent approaches of different countries and refers to the drug affordability and accessibility issue citing the case of Hepatitis C drug by Gilead which recently got a patent in India.

   Governments and generic companies in countries like Egypt — where millions live with the virus and suffer from symptoms such as cirrhosis, liver failure and cancer — have developed a strong political will to make and market low-cost DAAs. They changed the way people think about quality generics. Indian manufacturers — which have a reputation for their reverse engineering skills and were the first to market low-cost versions of life-saving cancer (imatinib) and HIV drugs (zidovudine) within two-three years of their US launch at the turn of the century — now face competition from Bangladeshi and Egyptian manufacturers. They launched the generic versions of sofosbuvir ahead of Indian companies in early 2015. Clearly, their governments were backing them using flexibilities available under WTO rules.

   But with one stroke the Indian Patent Office's decision to grant the patent on the base compound of sofosbuvir this week has provided Gilead with the tools to disrupt and stop future exports of the API from India, giving it significant control on the supply of API globally. India's decision to reverse the patent rejection of 2015 to an order for grant in 2016 is going to cause short-term pain to producers in Egypt and other countries, which will now have to find alternative sources. But, intriguingly, it also undermines the government's recent efforts and policy to revive and boost the domestic API industry.

10. **Centre to start 100 generic medicine outlets in states** – Hindustan Times
    The central government will open 100 generic medicine stores in Maharashtra. The government will also give a subsidy of Rs2.5 lakh to those interested in setting up shop, Union minister for chemical and fertiliser Ananth Kumar declared on Monday. He also announced opening of

medical devices park in Nagpur, bulk drug park in Aurangabad, a new campus of National Institute of Pharmaceutical Education and Research (NIPER) in the state and two centres of Central Institute of Plastic Engineering and Technology (CIPET) in Pune and Jalgaon. The Narendra Modi-led BJP government has decided to start 300 generic medicines across the country and 100 of them will be in Maharashtra. The central government has also decided to start a plastic park in Chandrapur to recycle plastic waste under Swachchh Bharat Abhiyan. The project gets an investment of Rs1,000 crore and generates employment for 1 lakh people.

11. **An IP Policy with no innovation** – The Hindu
    An opinion piece by Shamnad Basheer, Founder of SpicyIP, shares his view on the recently announced IPR policy. He views the policy as a biggest flaw in terms of accelerating innovation in certain technology sectors and impedes it in others. India has been attempting to break this mould and craft a regime to suit its own distinctive set of concerns. Section 3(d) of the Patents Act, 1970, was a bold attempt in this direction, aimed at eradicating "evergreen" drug patents. Sadly, this distinct attempt at diversifying a problematic global IP script is slowly yielding to larger market forces. It is reinforcing a realpolitik predicated to a large extent on various campaign contributions flooding the coffers of candidates striving to lead the most powerful democracy of the world, namely the U.S. The policy fails to situate IP within the larger context of the innovation ecosystem, refusing to acknowledge that while IP could accelerate innovation in certain technology sectors, it impedes innovation in others. This is a truth touted not only by those labelled as left-liberal ideologues, but powerful industry giants facing the brunt of a promiscuous patent regime — renowned giants such as Tesla's Elon Musk who have either eschewed patents or dedicated them to the public domain. The policy needs to be commended for taking note of our "informal" (rural) economy and the need to encourage the prolific creativity found within. Unfortunately, far from understanding the drivers of creativity and the modes of appropriation/sharing in this "shadow" economy, the policy leans towards the superimposition of a formal IP framework on this marginalised sector. Unfortunately the government unceremoniously disbanded our committee after we submitted the policy and disregarded our exhortation to conceive of the policy as a more broad-based and holistic Innovation Policy. Compare and contrast that with the present policy that took more than two years and two separate think thanks to come to fruition. One beset with banality, dogged by dogma, rife with ridiculous assertions, lacking in any credible empirical support, and written in language that, at best, mimics a masterful memo from one babu to another.

12. **CoA members of Pharmexcil seek govt intervention on issues related to election of chairman, vice-chairman** – Pharmabiz.com
    The Committee of Administration (CoA) members of the Pharmaceuticals Export Promotion Council of India (Pharmexcil) have urged the Union commerce ministry to intervene in the election procedure for the post of vice-chairman of the council as per para 2.92 of Foreign Trade Policy (FTP) 2015-20. The CoA members are upset with the recent notification of Pharmexcil to conduct the election for the post of chairman, along with the post of vice chairman as in the recent emergency meeting of CoA the council decided to conduct an election only for the post of vice chairman. But the notification to conduct the election for the post of chairman without any prior intimation has forced most of the CoA member to raise an objection. The Council had held an emergency meeting on April 26, 2016 with its member for the implementation of FTP para 2.92 which states that the all Export Promotion Councils (EPCs) have to follow the criteria of e-voting for the post of vice chairman/vice president and executive committee members to continue functioning as registering authority and get grants under MIA and MDA schemes.