1. **No plea from pharma industry to resolve issues with USFDA: Government** – Economic Times

   Domestic pharmaceutical industry has not approached the government for early intervention to resolve regulatory issues faced by them in the US. "There is no representation from the industry to the government for early intervention and dialogue with the US health regulator," said Minister of State for Commerce and Industry Nirmala Sitharaman. The USFDA has refused entry of 12,012 Indian products, including drugs, into the American market between January 2011 and March 2016 for various reasons. The reasons given for the refusal include misbranding, adulteration, packaging, labelling, pesticides, unapproved products and the like.

2. **385 Indian applications for trademark registration in FY16** – Economic Times

   The World Intellectual Property Organisation (WIPO) received only 385 applications from the Indian entrepreneurs aspiring to have their trademarks registered globally during the year 2015-16. On the other hand, 24,000 international registrations sought protection of trademarks in India in this period. Controller general of patents, designs and trademarks O P Gupta, “Unfortunately, we have received merely 385 applications from Indian entrepreneurs so far and out of which, 265 applications have already been processed by WIPO”.

3. **Health Ministry panel rejects Sanofi's clinical waiver plea for dengue vaccine** – ETHealthWorld.com

   Although the Sanofi vaccine does not qualify for a waiver of clinical trials, SEC had recommended market authorisation, “considering the fact that dengue is a health problem of major concern in the country and can be life threatening in certain cases.” French drug and vaccines giant Sanofi suffered a setback in introducing its much awaited dengue vaccine Dengvaxia in India after a top health ministry committee rejected its request to waive additional clinical studies. The decision of the apex committee is expected to delay the entry of the vaccine, which has been approved in Mexico, the Philippines and Brazil to combat the

mosquito-borne disease. The apex committee took a more cautious view and noted that 'evidence in the present case is not sufficient to waive conduct of clinical trial in the country." "Given the urgency of dengue in India, we are optimistic that we can work with the Indian regulatory authorities to find the best regulatory solution that allows us to increase the clinical data on our dengue vaccine in the Indian population, without delaying access," a Sanofi India spokesperson said.

4. **India ratifies WTO trade facilitation agreement: Nirmala Sitharaman** – Mint
   TFA sets out measures for effective cooperation between customs and other authorities on trade facilitation and customs compliance issues. “India has ratified the trade facilitation agreement (TFA) of the World Trade Organization and the instrument of acceptance for trade facilitation agreement was handed over to WTO director-general by India on April 22, 2016,” said Minister of State for Commerce and Industry Nirmala Sitharaman. On the India European Union Bilateral Trade and Investment Agreement (BTIA), Sitharaman said negotiations are underway and 16 rounds of negotiations have been held so far.

5. **IMS-Quintiles merger to give big data support to clinical research** – The Hindu Business Line
   The proposed $9-billion merger between data-cruncher IMS Health and contract research organisation Quintiles Transnational may not seem like a perfect fit at first glance. The deal creates a mammoth, Quintiles IMS Holdings Inc, with a market value estimated at $18 billion. The clincher is that the combined entity will house research skills sharpened by analytical data on medicines, its distribution, the people consuming the medicines and those prescribing it. With company top brass defining it as a “transformational merger of equals”, industry veteran Shoibal Mukherjee observes that the deal keeps its eye on the future where data is big and analyzing it, getting conclusions and channeling it into research will help drive the business. The combined company will now be better placed to provide a seamless platform of data and research across healthcare. With company top brass defining it as a “transformational merger of equals”, industry veteran Shoibal Mukherjee observes that the deal keeps its eye on the future where data is big and analyzing it, getting conclusions and channeling it into research will help drive the business. The combined company will now be better placed to provide a seamless platform of data and research across healthcare.

6. **Global cancer meet to discuss new therapy** – The Hindu Business Line
   Tata Memorial Centre (TMC) is hosting the fifth ‘Biennial International Metronomic and Anti-Angiogenic Meeting’ between May 6 and 8, which is being held in India for the first time. Doctors at TMC said while research and trials are underway to map the efficacy of metronomic therapy, some benefits have already been documented including its cost-effective nature and that it works better in controlling the disease while increases life expectancy with lesser side effects. He said there are 150 trials underway across the world to test metronomic therapy and its efficacy, but given the nature of cancer and the possibility of its recurrence, it will be some time before the findings can be considered conclusive.

   Similar story in Indian Express: 350 oncologists to discuss non-cancer medicines in cancer treatment at Mumbai’s Tata Memorial Hospital

7. **Call for compulsory licence on Novartis blood cancer drug in Colombia** – The Hindu Business Line
   A call for a compulsory licence (CL) on Novartis blood cancer drug Gleevec has been made by Colombian civil society groups at a World Health Organisation meeting, in Geneva, that India is chairing. “Since November 2014, the undersigned organisations have been requesting the Ministry of Health of Colombia to declare the access to Imatinib (Gleevec(R)) of public interest with compulsory licence purposes,” a note from the organisations said. After 15 months of an extended process, the ministry acknowledged that access to Imatinib is a matter of public interest, a prerequisite to move to a CL. The WHO’s Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) meet is presently underway in Geneva.

8. **Indians unprepared for health emergency: Survey** – Mint
   Even as the country topped the overall well-being index, Indians are not ready to face unexpected expenses. India was ranked first in a survey focusing on monitoring and tracking motivations, perceptions and attitudes towards overall well-being among consumers across 11 countries. However, more than half of the respondents said they were unprepared for medical exigencies. India ranked highest in overall well-being in the region at 72.8, which was above the regional average of 65.3 in a league of overall well-being score results across 11 countries. The countries surveyed were China, Hong Kong, Indonesia, India, New Zealand, Spain, South Korea, Taiwan, Thailand, Turkey, and the UK.

9. **Partner the Private Sector: PPP is win-win, government cannot deliver universal healthcare on its own** – The Times of India
   Kiran Mazumdar Shaw in her write up highlights the challenges faced on delivering universal healthcare and role of PPP in contributing towards this initiative. Lack of resources, eg. Doctors vs citizen ratio, child mortality, public health spending are among some that she refers to. In terms of solution, she says, India needs a universal healthcare programme that hinges on affordability and access. This calls for existing public health infrastructure to be revitalised, new medical centres built and modern ICT-based telemedicine technology to be leveraged for addressing the demand-supply gaps in terms of doctors and health facilities. There is an urgent need therefore for public health spending in India to be raised to at least 2.5% of GDP as well as Public Private Partnership (PPP) models in healthcare to be promoted.

10. **Bitter medicine for the Centre** – The Hindu
    An editorial in The Hindu shares opinion on the recent overhaul of the MCI in India. The Supreme Court has given the Centre a deserved rebuke by using its extraordinary powers and setting up a three-member committee headed by former Chief Justice of India R.M. Lodha to perform the statutory functions of the Medical Council of India. The government now has a year to restructure the MCI, the regulatory body for medical education and professional practice. The Centre's approach to reforming the corruption-afflicted MCI has been wholly untenable; the Dr. Ranjit Roy Chaudhury expert committee that it set up and the Parliamentary Standing Committee on Health and Family Welfare in the Rajya Sabha had both recommended structural change through amendments to the Indian Medical Council Act. The single most important issue that the Lodha committee would have to address is corruption in medical education, in which the MCI is mired. Appointing prominent persons from various fields to a restructured council would shine the light of transparency, and save it from reverting to its image as an "exclusive club" of socially disconnected doctors.

11. **Pharma industry needs to use patent information to reduce R&D costs: Bindu Sharma** – Pharmabiz.com
    Indian pharma industry will need to use information available in the form of patents to reduce research and development costs, said Bindu Sharma, patent attorney and chief executive officer, Origiin IP Solutions LLP, Bengaluru. In the current competitive market scenario, the drug manufactures require a high degree of innovation in product development. Only novel products can sustain in the market for longer period of time, Sharma told Pharmabiz. Innovation is adopted as a major strategy to achieve a competitive edge in the market. Expectation of the consumer on one hand and competition on the other hand puts a lot of pressure on pharma companies to bring new products to the market, she added. "Since patents undergo various stages like publication, examination and grant of patent several statutory requirements are to be met. This is where 'state-of-the-art' is a power tool that can be used to bootstrap core technologies and reduce R&D cycle, she noted.

12. **Health activists slam US report which puts India on priority watch list for IPR Protection** – IBTimes.com
    Health activists have slammed the United States' move of putting India on the priority watch list of countries for inadequate protection of intellectual property rights (IPR). The activists have been quoted by Economic Times as saying that any change in the patent laws would affect the production of affordable medicines in the country and their access to millions of people

worldwide. Medecins Sans Frontieres (MSF), an international medical humanitarian agency, and various health activists based in India have pledged their support to the existing Indian patent laws and slammed the U.S. report. "India's laws and policies promote generic competition and limit abusive pharmaceutical industry practices, including patent 'evergreening', and are entirely compliant with World Trade Organisation (WTO) trade rules," the Economic Times quoted MSF as saying in an official statement.