

1. [Positive USFDA Reports Pep up top Indian Pharma](#) – Economic Times

Lupin, Torrent, Aurobindo and 4 others will resume supplies to the US as their manufacturing facility inspections have reached successful closure. Experts viewed the feedback as positive but cautioned that frontline companies like Dr Reddy's, Sun Pharma and Cadila Healthcare are yet to gain due clearances and the remediation process should be seen as a "work in progress". "FDA has deployed in-country inspectors and stands responsible for the quality of drugs. Therefore, Indian suppliers may be hauled up for observations and that should be seen as a routine exercise," said an independent QAQC consultant, asking not be identified as he was involved in remediation plan of a mid-sized firm. "The lessons are learned but the frequency of really serious issues will plateau out over time". The importance

of the US market for India drug companies cannot be overstated. In a note in April, the same agency had said, "Increased regulatory scrutiny as reflected in growing issuance of warning letters import alerts (by US FDA) and consolidation of supply chain in US market resulting in pricing pressures will have an impact on competitiveness of Indian pharmaceutical companies."

2. [Soon, mechanism to check prices of cardiac stents](#) – ETHealthWorld

Keeping patient welfare in its perspective given the high degree of exploitation in costs of life saving stents, the finding of the committee are expected to fast track the decision on the subject. On 2nd June 2016 a Rajya Sabha Committee met in Bengaluru on the petition to check exorbitant prices of cardiac stents and other subjects. Honorable Members of the Rajya Sabha Committee, Senior Officials from Department of Pharmaceuticals and Ministry of Health, and industry representatives were present. Representations from Indian manufacturers, foreign manufacturers on stents and also from Government Officials were made. The members of the Rajya Sabha Committee were quite convinced that there should be a mechanism to check exorbitant costs on cardiac stents to safeguard patient's interest while promoting cost effectiveness in industry.

3. [Staff under various heads of National Health Mission to be integrated](#) – Mint

Health ministry will save funds through rationalisation of services which will be available for other purposes. The Union health ministry will integrate its staff under the National Health Mission (NHM) working on various programmes under a single umbrella, a ministry official said. The move will check duplication of staff in some places, while opening up possibility of round-the-clock services where it is required. Currently, different heads under NHM such as Revised National Tuberculosis Control Program (RNTCP), National Vector Borne Disease Control Programme (NVBDCP) and Reproductive Child Health (RCH) have their own workforce. Thus, in one location, say a primary health centre (PHC), there are several lab technicians to perform different tests.

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3. [Staff under various heads of National Health Mission to be integrated](#) – Mint
4. [Delhi HC reserves judgement on fixed combination drugs ban](#) – Mint
5. [A policy without intellectual clarity](#) – Hindu Business Line
6. [Soon, med devices may need licence to be sold](#) – Times of India
7. [Rise in patents from India for essential drugs may hurt affordable treatment](#) – The Times of India
8. [NGO's urge PM to 'resist pressure' from U.S. on IPRs](#) – The Hindu
9. [Global cancer drug spending to exceed \\$150 billion by 2020: IMS report](#) – Times of India

4. [Delhi HC reserves judgement on fixed combination drugs ban](#) – Mint  
Centre maintained that ban was imposed in public interest as the combination drugs were not safe for health and had been banned in various other countries. The Delhi high court on Thursday reserved its order on the validity of a recent ban imposed by the health ministry on 344 fixed dose combination (FDC) drugs. The Centre maintained that the ban was imposed in public interest as the combination drugs were not safe for health and had been banned in various other countries. Accordingly, it was contended that the drugs were banned under Section 26(A) of the Drugs and Cosmetics Act, 1940, which allowed the Centre to regulate, restrict or prohibit the sale of any drug if it was satisfied that it posed a risk to health or that it had no therapeutic justification.
5. [A policy without intellectual clarity](#) – Hindu Business Line  
The IP policy is all for turning knowledge into IP assets, not realising that public access and equity are central to creativity. The author, a professor of Law at Texas A&M University School of Law shares comments on the recommendations made in the IPR policy. According to her, ‘the suggestion in a national policy to “spread the importance of IP rights” by using “eminent personalities as ambassadors” reflects a deplorable level of over-anxiousness on the part of the Government to promote private rights. She suggests, that Government policies should establish appropriate standards to facilitate IP protection while balancing it with carefully calibrated filters to ensure that access to public goods such as medicines, health technologies, food security and environmental safety are not unduly impeded. India’s over enthusiasm for promoting IP rights should not discount the reality that even in the US, there is an outcry to balance social and economic justice. Unfortunately, instead of discussing how the carefully instituted flexibilities have and will continue to posit India in a superior position as the pharmacist of the world, the discussion digresses towards protection for traditional knowledge in a policy discussing IP rights. It begs the question of why “commercial courts and appropriate levels” were not fully considered when valuable tax payer resources were invested previously to establish the Intellectual Property Appellate Board.
6. [Soon, med devices may need licence to be sold](#) – Times of India  
Medical devices such as stents, catheters, orthopaedic implants, heart valves and syringes are set to face stringent scrutiny as the government plans to make regulatory approval mandatory for all such products sold in the country, sources said. The proposal, once implemented, can be a major blow to the medical devices industry, pegged at over Rs 47,000 crore. The government has already finalised a plan to set up a testing laboratory for medical devices in Vadodara (Gujarat). The laboratory-first of its kind in India-will also certify medical devices approved and sold in India. The government may also outsource part of the quality certification process to standardising bodies such as BIS or some global solution providers.
7. [Rise in patents from India for essential drugs may hurt affordable treatment](#) – The Times of India  
Increase in patents on essential medicines in India will jeopardise supply of affordable treatment, not only in the country, but also in developing nations. The latest trigger raising concerns among public health advocates is exorbitantly-priced hepatitis C drug sofosbuvir by Gilead, which was recently granted a patent in India, despite opposition by civil society and generic companies. The issue was highlighted in a recent editorial in medical journal Lancet, while the access and affordability of hep C treatment was debated at the recently-concluded World Health Assembly. The editorial strongly supports the use of compulsory licenses, voluntary licenses and other flexibilities available to countries to increase access to essential medicines. "If countries want to provide treatment for hepatitis C and the price is too high because there is a patent in their country and the patent holder refuses to lower the price or offer a voluntary license to access generic supply, they should issue a compulsory license (CL) and go ahead with buying from Indian companies at lower price," the author says.
8. [NGO’s urge PM to ‘resist pressure’ from U.S. on IPRs](#) – The Hindu  
A group of civil society organisations has urged Prime Minister Narendra Modi to ‘resist,’ what they termed, “pressure from the U.S. and the pharmaceutical multinationals based there to amend India’s Intellectual Property Rights (IPR) laws”. The appeal comes ahead of Mr. Modi’s

U.S. trip next week when the issue of greater protection and enforcement of IPR may come up for discussions. The group also wanted the NDA Government to ensure transparency regarding its engagements with the U.S. on IPR issues by tabling a White Paper in Parliament. They said the recently announced National IPR Policy “sees the generation of IPRs as an end in itself. However, in reality, promotion of IPRs has not only limited the ability of developing countries to obtain critical technologies for their economic and social development but has also seriously impacted their peoples’ lives by making essential goods such as medicines, seeds, and textbooks unaffordable.”

9. [Global cancer drug spending to exceed \\$150 billion by 2020: IMS report](#) – Times of India

Worldwide spending on cancer medicines will exceed \$150 billion by 2020 , driven by the emergence of expensive new therapies that help the immune system to attack tumors, according to a global oncology report released by IMS Health Holdings on Thursday. That represents an annual global growth rate for oncology drug spending of 7.5 percent to 10.5 percent through 2020, up from last year's IMS forecast of 6 percent to 8 percent growth through 2018. The figures are based on the medicines' list prices, which exclude discounts and rebates, and also include supportive care drugs to address side effects like nausea and anemia associated with many treatments, particularly chemotherapies.