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1. **Govt's plan to take over drug price regulator's powers raises questions – Mint**

The NITI Aayog's proposal to take away the drug-price-fixing powers vested in the National Pharmaceutical Pricing Authority (NPPA), discussed at a meeting over a month ago, may not succeed, officials from the department of pharmaceuticals (DoP) and the health ministry said on condition of anonymity. The October meeting, involving NITI Aayog chief executive Amitabh Kant, pharmaceuticals secretary Jai Priye Prakash, health secretary C.K. Mishra and department of industrial policy and promotion secretary Ramesh Abhishek, had mooted the plan to subsume NPPA into the DoP and give it a new mandate, while the ability to control prices of drugs would be given to the government.

"Such a move would be difficult to manoeuvre since it would result in a conflict of interest between the government's need to promote the pharmaceutical industry and its mandate to protect public health needs. That's the reason why there are separate bodies handling different aspects of price control," said a senior government official.

2. **Govt invites domestic pharma firms to set up bulk drug clusters – Business Standard**

The department of pharmaceuticals has invited an Expression of Interest (EoI) from companies to set up clusters largely for producing bulk drugs.This is the fourth such phase; the earlier ones weren't a hit with the pharma industry. The cluster scheme is a public-private partnership (PPP) project, where the government will fund up to 70 per cent of the project cost, subject to a ceiling of Rs 20 crore, to set up a cluster. The project aims to set up common facilities for companies and upgrade any existing one.

In the ongoing five-year plan (2012-17), an amount of Rs 125 crore was allocated for this cluster development scheme. The effort is part of the aim to bring down India's dependence on China for bulk drugs. The country imports 65 per cent of this requirement from there, Rs 13,853 crore in 2015-16.

3. **HC to pronounce tomorrow order on pleas against 344 FDCs ban – Business Standard**
The Delhi High Court is likely to pronounce tomorrow its verdict on 454 petitions filed by drug and healthcare majors challenging the Centre's decision to ban 344 fixed dose combination (FDC) medicines, including well known brands like Corex cough syrup, Vicks Action 500 extra and D'Cold.

Justice Rajiv Sahai Endlaw on June 2 had reserved the order after hearing regular arguments of companies like Pfizer, Glenmark, Procter and Gamble and Cipla, the central government and some NGOs like All India Drug Action Network (AIDAN) over a span of over two months, starting from March 14. The court had on March 14 stayed the Centre's March 10 ban on 344 FDC drugs and this interim order was passed in each and every case filed before it thereafter.

4. **No cash for counter: Online drug sale booms despite ban – The Times of India**
Though online sale of drugs has been banned under Drugs and Cosmetic Rules, 1945, city pharmacy chains are taking advantage of the demonetisation by offering attractive discounts to customers on prescription drugs. Discount offers from 10% to 20% are available for patients online if they visit http:www.apollopharmacy .in, http:www.medplusmart.com and https: http:www.1mg.com offers respectively .This has left members of All India Organisation of Chemists and Druggists (AIOCD) infuriated as they reiterated that online pharmacies are not only against rules but it would lead to the unregulated sale and misuse of steroids and habit forming drugs.

5. **TB: Govt. to tighten regulatory mechanisms – The Hindu**
The government, as part of the World Health Organization's End TB Strategy, is tightening the regulatory mechanisms to curb improper prescribing practices of anti-tuberculosis drugs and engage the private sector physicians better so that every case of TB in the State is accounted for. Even though TB is officially a notifiable disease in the country since 2012, a good number of cases which are diagnosed and treated by private sector physicians never get accounted for, as these cases are not entered into NIKSHAY, the Health Ministry's official Web-based TB case notification network.

6. **For people living with HIV, fear of stigma a deterrent in seeking govt. Entitlements – The Hindu**
Stigma and discrimination continue to pose access barriers for people living with HIV (PLHIV). They face various vulnerabilities such as job insecurity, poor access to healthcare facilities, and low access to nutritional support and education for children. In addition, stigma and discrimination diminish their access to work and medical treatment and also lower their self-esteem to even seek government entitlements. In Karnataka, although the State government has introduced various social security schemes, not many people living with HIV are keen on seeking the benefits mainly because of the fear of stigma and discrimination.

7. **U.S. House passes 21st Century Cures health bill – Reuters.com**
The U.S. House of Representatives on Wednesday passed a sweeping, $6.3 billion bill that supporters say will spur medical innovation, speed access to new drugs, expand access to mental health treatment and battle the opioid epidemic. The bill, known as the 21st Century Cures Act, had widespread bipartisan support, including the backing of the Obama administration, though critics said it gives massive handouts to the pharmaceutical industry while making cuts to public health programs and Medicare.

8. **Sun Pharma, Cadila Healthcare recall products from US market – Mint**
The US-based subsidiaries of two domestic drug firms—Sun Pharma and Cadila Healthcare—are recalling one product each from the market on account of failure to meet the desired specification norms. Zydus Pharmaceuticals USA Inc is recalling 2,472 units of Bupropion Hydrochloride extended release tablets manufactured by Ahmedabad-based Cadila Healthcare, the latest Enforcement Report of the USFDA has said. Bupropion Hydrochloride extended-release tablets, USP (XL) 300 mg

are being recalled by Zydus Pharmaceuticals USA Inc on account of "failed dissolution specifications: product did not meet dissolution specification at an intermediate time point", it added.

9. **Medical device industry rues recommendations not incorporated in the draft for new Medical Device Rules – Pharmabiz.com**

   Government must consider industry recommendations for Medical Device Rules to circumvent severe jeopardy to critical healthcare in India and it falls short of the expectations of the medical devices sector, feels the industry. In a statement, the industry experts say that the Medical Device Rules were initially prepared with industry consultation, however the comments of the industry as well as certain elements where agreement was obtained between industry and Health Ministry officials were not incorporated in the draft that was published on October 17th, 2016 for stakeholder's comments (within 30 days).

   "In their current form the Medical Device Rules could severely jeopardize the continued supply of critical care medical devices to India. They will also endanger the huge investments made in Manufacturing in the country by global companies & will dent the FDI which has been growing multifold since it was sagaciously brought on the automatic route by the current government. Having said that, we are engaged with the Health Ministry as well as the CDSCO on the Rules, and if the past is anything to go by, their inclusive approach and nuanced understanding of the issues will help us once again reach solutions so that the supply of critical care devices will continue uninterrupted to the Indian patient," commented Pavan Choudary, director general, Medical Technology Association of India (MTaI) in a statement.

10. **DTAB makes validity of various licences, approvals granted under D&C Rules forever – Pharmabiz.com**

    The Drugs Technical Advisory Board (DTAB) has given green signal for the health ministry's proposal to make amendments in Drugs & Cosmetics Rules, 1945 to make the validity of various licences and approvals granted under the D&C Rules forever unless otherwise suspended or cancelled by the licensing authority. By making these amendments, the ministry wanted to further improve the quality of services provided by the drug regulatory authorities in the country.

    In its 74th meeting held on November 15, 2016, the DTAB agreed for the proposal that the manufacturing and sale licences once issued, shall remain valid forever, unless suspended or cancelled by the Licensing Authority subject to certain conditions. They include, such inspection for grant of licence shall be carried jointly by state and Centre involving relevant experts of respective area considering the category of the drug for GMP/GLP inspection; and such licensees shall be subjected to minimum of one annual inspection until unless justified otherwise on the basis of risk evaluation.