

1. [Drug regulator maps out new site inspection norms for safer medicines](#)

– Economic Times

The Central Drug Standard Control Organisation (CDSCO) is drawing up a new inspection model for pharmaceutical manufacturing sites that will help identify compliance issues and products that can be potentially harmful. The move follows concerns raised by foreign drug regulator . over quality of medicines produced in India. According to some GMP experts, CDSCO's proposed move may be different from the risk-based inspection system followed by the US Food and Drug Administration (FDA), where a site that has been inspected lesser may be considered to be at a higher risk for compliance issues and evaluated on a higher frequency. CDSCO is currently in the process of imparting training to drug regulators and analysts from state and central governments based on this document. Quality-related lapses are among the main threats to the pharmaceutical industry here and are not limited to Indian drug makers. This month,

among other orders, the CDSCO directed a withdrawal of four batches of global drug maker Sanofi's popular painkiller Combiflam from the market after finding them to be sub-standard.

2. [Kanchana TK appointed new Director General of OPPI](#) – ETHealthWorld.com

Kanchana brings a new strategic perspective to India's evolving healthcare policy ecosystem. The Organisation of Pharmaceutical Producers of India (OPPI), which represents the research-based pharmaceutical companies, has appointed Kanchana TK as its new Director General, with effect June 01, 2016. Kanchana takes over from Ranjana Smetacek, who has decided to relocate to USA. Dr Shailesh Ayyangar, President, OPPI said, "I would like to thank Ranjana for her professionalism and leadership over the last three years at the OPPI and I am delighted to welcome Kanchana as her successor. With her sound experience in two highly-regulated sectors, insurance and pharmaceuticals, Kanchana brings a new strategic perspective to India's evolving healthcare policy ecosystem."

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3. [Indradhanush programme to be renamed](#) – Economic Times
Health Ministry's ambitious programme 'Mission Indradhanush', which provides immunisation against seven life threatening diseases, is all set to be re-christened as the addition of four new vaccines into its basket. 'Mission Indradhanush' depicting seven colours of the rainbow provides vaccination to seven vaccine preventable diseases which include diphtheria, whooping cough, tetanus, polio, tuberculosis, measles and Hepatitis B. Health Minister J P Nadda said that since four new vaccination has been added to the immunisation programme, its name has to be changed. To accelerate the process of immunisation by covering 5 per cent and more children every year, a "Mission Mode" has been adopted to achieve target of full coverage by 2020, they said. Nadda said that his Ministry has been working "aggressively" in various sectors including public health, tertiary, secondary healthcare and Non Communicable Diseases (NCDs).
4. [Delhi HC hears further arguments by Pharma firms against FDC drug ban](#) – Business Standard
Centre had notified a ban 344 fixed-dose combination drugs, impacting large pharma firms such as Pfizer, Abbott, GSK and Cipla. The Delhi High Court continued hearing petitioner rebuttals to the central government's stand in the FDC (fixed dose combination) drug ban case. Senior Advocate Gopal Jain, submitted that the statute contained an in-built doctrine of proportionality, which specifically provided for safeguards from unreasonable government action. "The act is a conclusive code with built in checks and balances, it needs to be followed strictly. In modern day governance, there is a well established need for full statutory compliance and transparency" Jain said. After hearing the arguments advanced, the bench presided by Justice Rajiv Sahai Endlaw further extended the interim orders previously advanced and listed the matter again for tomorrow in an attempt to expedite proceedings before the close of the court for the summer vacation.
5. [Ranjit Shahani: Price cap on drugs counterproductive](#) – Business Standard
Authored article by Ranjit Shahani: To ensure equal access to health care, the government must consider it in a holistic manner and improve all parameters. India is the fourth fastest growing economy in the world. A growing middle class, rising income levels and increased life expectancy are all indicators of a developing country. Unfortunately, rising affluence has also led to an increase in chronic and lifestyle-related diseases. The pharmaceutical industry, and the medicines it manufactures and markets, play an important role in addressing the health care needs of our population. While the DPCO is an attempt to regulate the industry, it should be noted that Indian drug prices are lower than in other developing economies and even the price increases have always been below or at par with inflation. The IMS health study found that the primary beneficiaries of price controls are high-income patients, rather than low-income ones. For low-income households that are reliant on the government system for health care, DPCO has had little or no effect on improving their ability to purchase drugs.
6. [We can be very aggressive when we get into US, EU market with our Biosimilars: Kiran Mazumdar Shaw](#) – Business Standard
We are front runners in the biosimilars race. If the market is not crowded, the kind of share you can take and the opportunity in pricing you enjoy will be rewarding. For the four biosimilars - Glargine, Trastuzumab, Pegfilgrastim and Adalimumab, the market opportunity is \$35 billion. Lilly has biosimilar insulin Glargine approval in Japan, Merck and Boehringer Ingelheim area also working on insulin glargine. It is nice to be on the top, because the others are all multinational companies and not generic companies. These companies are actually developing the insulin Glargine for completing the portfolio.

Global Pharma throws in the entire cost of the drug development R&D costs, marketing costs, operating costs and amortise the costs of drugs across the pipeline, even if one drug succeeds.

7. [Free trade pact: India to work with EU to sort out 'issues'](#) – The Hindu Business Line
India is ready to work with the European Union (EU) to sort out "issues of concern" related to the proposed bilateral free trade agreement. "The EU Trade Commissioner, in her letter, has

said that the bloc does not have any pre-conditions, but would want some issues to be sorted out. We want to work together with the EU. We want the agreement (the proposed free trade pact) signed," Commerce & Industry Minister Nirmala Sitharaman said during her address to the media on the two-year achievements of the NDA government on Monday. The EU wants India to give some commitments on lowering of import duties on automobiles before the BTIA negotiations restart. While India agreed that a working group be formed to look at the issue, it wants commitments on tariff cuts to be part of the negotiating process. The EU wants India to commit to sharp cuts in import duties on automobiles, currently ranging between 60 per cent and 120 per cent, as opposed to 10 per cent duties levied by the bloc.

8. [Pharma sector set for wave of mergers, acquisitions: Study](#) – The Times of India
The pharmaceuticals sector is facing an intensive period of mergers and acquisitions in the coming years, even if US firms Pfizer and Allergan recently failed to tie the knot, the corporate consultancy firm EY said Monday. "Pharmaceutical groups can only present innovations quickly if they buy these from outside," Bialojan argued. After a record year for M&A (mergers and acquisitions) in the pharmaceuticals sector in 2014, 2015 would have been even better if the tie-up between Pfizer and Allergan had materialised. Also in the US, Abbott Laboratories and St. Jude Medical, leading makers of heart care and coronary devices, announced a \$25 billion merger to better target the rising levels of cardiovascular disease in aging populations.
9. [Govt scales up free drug budget for poor this fiscal](#) – New Indian Express
The State Government has decided to supply medicines and surgical items worth around Rs 239 crore to poor patients free of cost in the current fiscal for which e-bidding would start shortly. Last year, free medicines worth around Rs 200 crore were distributed to patients. Managing Director of Odisha State Medical Corporation Limited (OSMCL) Parameswaran B said this time, the purchase will be based on consumption instead of indent to check piling of stocks at hospitals. To make the bidding process fair and transparent, the Corporation will have a pre-tender meeting with suppliers and interested bidders on June. Thereafter, they can participate in the online bidding process from June 7 to July 4. The bidding document has already been uploaded on OSMCL and NIC websites.
10. [AIOCD asks DoP to give direction to NPPA to notify drug price revision 3 months in advance](#) – Pharmabiz.com
The All India Organisation of Chemists and Druggists (AIOCD) has asked the Department of Pharmaceuticals (DoP) to give a direction to the National Pharmaceutical Pricing Authority (NPPA) to issue drug traders notification regarding decline in drug prices as per reduction in wholesale price index at least three months in advance to avoid any inconvenience caused to them in implementation of price revision. The Organization will soon submit a memorandum in this regard to the DoP. AIOCD in its memorandum will also seek the DoP's intervention to direct NPPA to issue circular to drug manufacturers asking them to stop production of medicines with batch number whose prices have been lowered as per Wholesale price index (WPI) and resume supply of the drugs with revised prices.