1. **OPPI reelects its office bearers – Biospectrum.com**

At the recently held Statutory Annual General Meeting of members of the Organisation of Pharmaceutical Producers of India (OPPI), Dr Shailesh Ayyangar, Managing Director India and VP South Asia, Sanofi was unanimously elected as the President for the year 2016-17.

Dr Ayyangar has held this position for the past three years. At the same meeting, four vice-presidents were elected unanimously - Mr Sudarshan Jain (Managing Director - Healthcare Solutions, Abbott Healthcare Pvt Ltd), Mr Sharad Tyagi (Managing Director, Boehringer Ingelheim India Pvt Ltd), Mr K. G. Ananthakrishnan (Vice President & Managing Director, MSD India) and Mr Sanjiv Navangul (Managing Director, Janssen India-Johnson & Johnson Ltd.). The elected office bearers of OPPI will have their tenure till the next Annual General Meeting in 2017.

2. **IPC 68th edition theme 'Quality Pharmaceuticals and Patient Welfare' to be recognised by PCI as CPE programme – Pharmabiz.com**

The 68th Indian Pharmaceutical Congress (IPC) scheduled to be held from December 16-18, 2016 in Visakhapatnam, Andhra Pradesh with its theme as 'Quality Pharmaceuticals and Patient Welfare' will be recognised by the Pharmacy of Council of India (PCI) as continuing pharmacy education (CPE) certificates. The annual event is hosted by the Indian Pharmaceutical Associations (IPA) and supported by the Commonwealth Pharmacists Association (CPA), Pharmexcil, the Indian Drug Manufacturers' Association (IDMA) and the Organization of Pharmaceutical Producers of India (OPPI).

3. **Now, new guidelines to prohibit drug-makers from sudden discontinuation of essential medicines – The Times of India**

In a move to ensure availability of essential medicines, including life-saving drugs, the drug pricing authority has come up with new guidelines prohibiting drug-makers from sudden discontinuation of such medicines to circumvent price control regulations. The National Pharmaceutical Pricing Authority has drawn a detailed set of norms categorising commonly used medicines based on their sales. It is aimed at ensuring that even if a manufacturer of any essential medicine wants to discontinue production, the drug remains in supply till consumers find an alternative. For instance,

the guidelines say if a drug has a market share of more than 10% and less than 20% and its manufacturer wants to stop selling it in India, the regulator will allow gradual discontinuation but the company will have to continue selling the medicine for at least nine months and not reduce production by more than 40%.

Similar report-

- NPPA approves norms for discontinuation of scheduled drugs – Business Standard

4. **Big Pharma vs Big Pharma in court battles over biosimilar drugs – Reuters.com**

The line dividing makers of brand-name drugs and copycat medicines is blurring as companies known for innovative treatments queue up to peddle copies of rivals' complex biological medicines. These drugmakers are now increasingly straddling both sides of the courtroom, too, protecting their high-price products from biosimilars - biopharmaceutical drugs with the treatment properties of medicines they seek to mimic - while simultaneously challenging rivals' patent claims. Biologics, manufactured in living cells, then extracted and purified, are more complex than traditional medicines and cannot be copied with precision, and so their knock-off versions are called biosimilars instead of generics.

Similar report-

- Big Pharma vs Big Pharma in court battles over biosimilar drugs – The Economic Times

5. **Drug regulator may step up ban on FDCs – Business Standard**

The drug controller has decided to ban more fixed dose combinations (FDCs) as recommended by the Chandrakant Kokate Committee. As a preparatory work, the Central Drugs Standard Control Organisation (CDSCO) has started issuing show-cause notices to companies, giving them opportunity to defend their FDCs, a senior official told Business Standard. The source added that this move is in line with the view that there is no place for “irrationality” and therapeutic justification in the drugs being sold. Around 70 show-cause notices have been sent to companies already, it is learnt.

Meanwhile, court verdicts are awaited on the various cases filed by pharmaceutical companies challenging the ban of 344 FDCs earlier this year. Earlier this month, the government decided to transfer all the FDC cases registered in various high courts to the Supreme Court.

6. **PET peeves: stirring up health concerns in a bottle – The Hindu Business Line**

It’s been precisely two years since a draft directive from the Health Ministry sought to replace plastic medicine containers with glass, especially in the case of drugs for children and old people. But that is proving to be easier said than done for the Centre, as pro-plastic and PET (polyethylene terephthalate) advocates make compelling scientific arguments on why they are the right choice for packaging.

Internationally, the mechanism to monitor and supervise the quality of plastic containers is stringent. The quality of plastic differs in India, and even if there are stringent regulations, he says, the trouble is not with the science, but with the implementation of the regulations.

7. **Eye on foreign pie, India to upgrade drug testing centres – The New Indian Express**

Seeking to cash in on the demand for cheap Indian drugs abroad, the government has decided to upgrade drug testing facilities in the country to the standards of the US Food and Drug Administration to facilitate better exports. Sources in the Union Health Ministry said that though Indian drugs have a huge market in African and Latin American countries, exports to the United States and the European countries were suffering as the medicines sometimes do not meet their standards. The guidelines for manufacturing practices were issued by the Drug Controller General of India (DCGI). The guidelines are proper water facilities, rodent control mechanism focus on separate manufacturing facility, among others. The inspections are being carried out jointly by CDSCO officials and state drug inspectors.

8. **Shortage of drugs for Wilson's disease, drug makers asked to fix local supply issue – Business Standard**
   The Central Drugs Standard Control Organization (CDSCO) on Friday called a meeting with Wilson's disease drug makers over the issue of medicine shortage in India. The manufacturers of D-Penicillamine were asked to focus on meeting domestic demands rather than focusing on exporting it to other countries. The companies which attended the meeting raised the issue of pricing pressure that made it difficult for them to sell the drug in India. A source from the regulator told Business Standard that the health ministry and the CDSCO will request Department of Pharmaceuticals to not regulate the prices of rare diseases such as Wilson's disease.

9. **International healthcare summit from Oct 3 in Greater Noida – Business Standard**
   The commerce ministry is organizing an international summit on healthcare sector from October 3 at Greater Noida with an objective to promote India as a premier global medical destination and services exports. The three-day second edition of 'Advantage Health Care India 2016 (AHCI 2016)' is the first ever summit on medical value travel being organized for promoting services exports from India, and will bring together stakeholders from 67 countries, the ministry said in a statement.

10. **Senior citizens policy to focus on healthcare – The Times of India**
    The Odisha state government on Saturday unveiled Senior Citizens Policy 2016, coinciding it with the International Day of Older Persons, with emphasis on social security, healthcare, food, shelter and recreation for elderly people. The government has also focussed on geriatric care and counselling service, day-care centres in the policy. "The policy will address concerns of senior citizens in a holistic and equitable manner. In this policy, the emphasis has been given on healthcare, security, housing and emotional needs of elderly," said chief minister Naveen Patnaik said after the launch here.

11. **Zydus Cadila inks pact with Medicines for Malaria Venture – The Hindu Business Line**
    Healthcare player Zydus Cadila (Cadila Healthcare Ltd) on Friday announced collaboration with Medicines for Malaria Venture (MMV) to develop the investigational antimalarial compound, MMV674253. Zydus will lead the development of the novel compound and MMV will provide support including scientific expertise and access to tools in the field of malaria drug development and delivery, a company statement said here. The aim of the collaboration is to provide an effective alternative to the current front-line antimalarial drugs for the treatment of uncomplicated P. falciparum malaria, artemisinin-based combination therapies (ACTs), which are under threat of resistance.

    Similar reports-
    - Zydus partners Swiss non-profit for malaria drug development – The Economic Times
    - After chikungunya, Zydus to now co-develop malaria drug – Business Standard

12. **Cipla gets 4 observations from US FDA for its three plants in Goa – Mint**
    Drug maker Cipla Ltd on Friday informed stock exchanges that said it got four observations from US Food and Drug Administration (US FDA) for three of its manufacturing facilities in Goa. “US FDA recently concluded audit of our three manufacturing facilities at Goa and has issued four observations across these three facilities,” the company said. The company didn’t specify the nature of the observations. Cipla said the observations were primarily “procedural in nature” and the company has already responded to these observations. “We continue to operate our facilities with a high-level of compliance and control,” Cipla said.

    Similar report-
    - Concerns aggravate for Cipla, Alkem – Business Standard