1. **Driving Innovation For A Healthier India** – Huffington Post

The time period set by the nations of the world in 2000 for achieving the Millennium Development Goals (MDG) comes to an end in December. Leaders from around the world met at the United Nations General Assembly in September to review the progress made and adopt the Sustainable Development Goals. Here I want to posit that encouraging and fostering innovation and research is crucial to achieving these goals.

To harness the vast research potential in India, the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology and the Bill & Melinda Gates Foundation, launched the Grand Challenges India (GCI) initiative in 2013 to promote and cultivate health innovation in the country. Under the initiative, the DBT and the Gates Foundation pledged an investment of up to US$25 million each, over five years, to promote innovations in vaccines, drugs, agricultural products and interventions related to improving maternal and child health.

2. **Drug cos get a final chance to register with pharma data bank** – The Economic Times

The government has given a final chance to pharmaceutical companies to register themselves with pharma data bank by December 15 and said failure to do so will invite penal action.

"The companies are hereby given a final opportunity to register themselves in IPDMS and fill all forms as required... on or before December 15, 2015," National Pharmaceutical Pricing Authority (NPPA) said in a notice on its website.

Failure to submit mandatory data in IPDMS -- also known as pharma data bank -- or returns prescribed under Drugs (Prices Control) Order, 2013, through the IPDMS "will attract penal action under the provisions of the DPCO 2013 read with EC Act 1955," it added.

3. **Indian drug majors vie for Teva's drug portfolio** – Business Standard

Top pharma companies from India including Cipla, Glenmark and Sun Pharma are exploring bids for the drug portfolio of world's largest generic player Teva Pharmaceutical Industries.

The portfolio on sale includes 35 generic products in the US market including oral solids, capsules, soft gels and hormones. Second round bids are due this week and the sale could fetch $500-800 million, according to a Bloomberg report.

4. **Dr Reddy's buys Intellectual Property Rights for anti-coagulant drug for $17.5 million** – The Economic Times
   Dr Reddy's has completed the purchase of worldwide exclusive Intellectual Property Rights (IPR) for Fondaparinux sodium, its generic anti-coagulant drug, from Australian partner Alchemia for $17.5 million (around Rs 115 crore).

   The company had earlier inked a term sheet for this transaction in September.

   Alchemia's shareholders approved the sale of Fondaparinux at the company's annual general meeting held on November 10, post which Dr Reddy's and Alchemia have executed a have executed a purchase and sale agreement, together with various patent assignment deeds, Dr Reddy's LaboratoriesBSE -1.87 % said in a statement.

5. **Regulatory submission for Sandoz' proposed biosimilar pegfilgrastim accepted by FDA** - Express Pharma
   Proposed biosimilar pegfilgrastim filing is the second of ten regulatory filings planned over the next three years

   Sandoz, a Novartis company and the global leader in biosimilars, announced that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) under the 351 (k) pathway for its proposed biosimilar to Amgen's US-licensed Neulasta (pegfilgrastim) — a recombinant human granulocyte colony-stimulating factor (G-CSF).

   Sandoz is seeking approval for the same indication as the reference product. Pegfilgrastim is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in patients with cancer (non-myeloid) who receive chemotherapy that can cause fever and a low blood cell count (febrile neutropenia). In the US, the incidence of febrile neutropenia is estimated to be more than 60,000 a year, accounting for nearly eight cases per 1,000 cancer patients. Approximately 1.6 million people per year in the US develop non-myeloid cancer.

6. **R&D spending by Indian Cos** – Pharmabiz.com
   Last month, Pharmabiz came out with a study of R&D expenditures of India's top 25 pharmaceutical companies during 2014-15. It shows that there has been a 28.8 per cent growth in R&D spending at Rs.9,250 crore by these companies during the last year which is almost 7 per cent of their combined turnovers. The research spending of Indian pharmaceutical companies has been steadily growing over the last 20 years. In terms of percentage of R&D spending to sales of these companies, it is not that impressive when compared to the R&D spending of 15 per cent on sales of international companies. The research spending of Indian companies has been mainly targeted at developing cost effective generics, biosimilars and novel drug delivery system products. And they have been successful at that considering the growth in the number of filings of ANDAs and DMFs in the US and other developed countries. For the nine months ended September 2015, Indian companies received final approvals for 113 ANDAs from US FDA as against 122 final ANDAs approval during the year ended December 2014. The companies which received a good number of ANDAs this year are Aurobindo Pharma, Lupin, Glenmark Pharmaceuticals, Alembic Pharmaceuticals, Jubilant Life Sciences, Natco Pharma, Sun Pharmaceuticals and Hetero Labs.

7. **Accreditation of ethics committees vital for high quality research & trials for new drugs, Dr Y K Gupta** –Pharmabiz.com
   Certification and accreditation of institutional ethics committees who approve clinical trials, clinical investigators and trial sites are vital for high quality clinical research and clinical trials of new drugs, medical equipments and procedures, according to Dr Y K Gupta, national scientific coordinator for Pharmacovigilance Programme of India (PvPI).

8. **Blog: Why the TPP could kill access to medicines** – Spicy IP
   The TPP, while zealously advocating transparency for national governments (See Article 18.9), was negotiated completely behind closed doors. This prevented any vigorous scrutiny of negotiating positions or the draft text by academics, civil society and other professionals. Given the egregious history of knowledge asymmetries and coercive politics in international IP law making, scholars and activists were immediately suspicious. Leaked drafts of the text confirmed these fears. For IP, the US was strongly advocating for the adoption of higher minimum standards, despite the inability of the developing countries in the group to implement the same without seriously impeding access to medicines for the poor majority in their countries [eg. Vietnam ranks 121 on the Health index even below Iraq]. Corporations, however, were consulted on some positions, and portions of the text seem to be the outcome of corporate lobbying. These attempts were fiercely resisted by public health advocates and global health professionals. This has resulted in some roll backs – however the treaty still scores major wins for Big Pharma.