1. Column: TPP lesson on political leadership – The Financial Express
2. Novartis eyes $2.5-billion hit from Gleevec copies – Hindustan Times
3. Documents show profit-seeking behind price hikes at Turing, Valeant – Reuters
4. Varanasi: Blinded patients were given Avastin despite alert – Hindustan Times
5. New U.S. rule a blow to Indian pharma exporters – The Hindu
6. Centre proposes steep regulatory fee hike for pharma units – The Hindu
7. Indian pharma market to reach $ 55 bn by 2020 – Business Standard
8. India Can Become A World Leader In Affordable Health Care: PM Modi – NDTV
9. Sun Pharma, Lupin launch generics in US – Business Standard
10. Aurobindo gets USFDA nod for arthritis drug – Business Standard
11. Article on the Internet of Things - Towards smarter healthcare – The Hindu

1. **Column: TPP lesson on political leadership** – The Financial Express

The Trans-Pacific Partnership (TPP) will be signed in New Zealand on February 4, 2016. After all 12 members—Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and the US—sign the agreement, it will be ratified by legislatures of each country. The members have decided to give themselves two years for ratification by their respective legislatures. Some other TPP members might find the going tough at home. Australia is among these countries. There has been fierce resistance to the intellectual property provisions of the TPP in Australia. It was largely the resistance from Australia that made the data protection period for biologic drugs to be frozen at five years in the TPP, instead of the twelve years that was demanded by the pharma research and manufacturer lobbies in the US. Longer data protection period for biologics would delay the introduction of their generics having implications for drug prices for consumers. These implications are serious for Australia as it heavily subsidises drugs under the Pharmaceutical Benefit Scheme (PBS) for its citizens. Drug prices have also been riling Canadians, as have been the investor-state-dispute-settlement (ISDS) provisions, low domestic content requirement for automobiles and lowering tariffs on Canadian dairy imports. The going will not be entirely smooth in the Canadian Parliament as well.

2. **Novartis eyes $2.5-billion hit from Gleevec copies** – Hindustan Times

An explosion of copycat generics of the blockbuster cancer drug Gleevec is likely to result the Swiss pharma giant, Novartis, taking an impact of as much as $2.5 billion on its annual sales, the company is learnt to have said.

The generic version of Gleevec was launched in the US recently by Sun Pharmaceuticals.

“For Gleevec, we assumed February entry of the first generic. We believe it will be exclusive for the first six months, and our working assumption is there will be multiple entrants after those six months,” Harry Kirsch, chief financial officer at Novartis told analysts in the company’s earnings call last week, according to some analysts who participated in the call.

Also appeared in Business Standard

3. **Documents show profit-seeking behind price hikes at Turing, Valeant** – Reuters
A decision by Turing Pharmaceuticals to increase profits by raising the price of a lifesaving drug by 5,000 percent drove some patient co-pays up to $16,000, according to excerpts of documents that congressional committee members made public on Tuesday. The excerpts, highlighted in memos released by Democrats on the powerful U.S. House of Representatives Committee in Oversight and Government Reform, give a rare behind-the-scenes glimpse into the business decisions behind drastic price increases at Turing and Canada-based Valeant Pharmaceuticals International Inc.

The increases sparked a major public outcry. Both companies now face federal investigations over drug pricing.

4. **Varanasi: Blinded patients were given Avastin despite alert** – Hindustan Times
The Avastin (bevacizumab) injection has emerged at the centre of the controversy surrounding five patients' loss of vision in one eye each after being administered an infected injection at Sir Sunderlal Hospital here. Avastin is not approved in India for use inside the eye (intra-vitrieal use for ophthalmology). The Drug Controller General (India) issued an alert on January 21 this year, asking the drug controllers in the states and union territories to monitor the movement of Avastin and its use in ophthalmology.

The notice says, "Reports have appeared in the media (that) the drug Avastin (Bevacizumab Injection) 100 mg/4ml, 400 mg/16ml vials manufactured and marketed by M/s Roche Product (India) Pvt Ltd have been used in the treatment of eye ailments through intra-vitreal route and this has led to loss of vision in certain patients at CH Nagri Eye Hospital Ahmedabad, Gujarat."

5. **New U.S. rule a blow to Indian pharma exporters** – The Hindu
In a move that will further inflate prices of drugs in the United States — already a burning issue in the current presidential campaign — the U.S. government has made it mandatory for Active Pharmaceutical Ingredients (APIs) to be manufactured locally. At present, nearly 80 per cent of drug raw material requirement is met by India or China.

The decision has already sent Indian pharmaceutical exporters into a tizzy, as it will significantly impact Indian drug exports. Before the new norms came into effect, U.S.-based companies were allowed to procure APIs from countries like India and China, make the fixed formulations (final product) in the U.S. and sell the drugs to the U.S. government.

6. **Centre proposes steep regulatory fee hike for pharma units** – The Hindu
A manifold increase in the regulatory fee for testing, manufacturing and selling medicines has been proposed by the Centre, something that Pharmaceuticals Export Promotion Council of India (Pharmexcil) apprehends will have serious implications.

Among the changes sought to be made are a steep hike in the application fee for inspection of the manufacturing premises from $5,000 to $25,000; from $1,000 for drug registration (single drug) to $5,000; and registration fee for premises from $1,500 to $10,000.

7. **Indian pharma market to reach $ 55 bn by 2020** – Business Standard
The pharmaceuticals market in India, valued at $ 20 billion in 2015, is set to soar to $ 55 billion by 2020, representing an impressive compound annual growth rate (CAGR) of 22.4 percent, according to the UK-based research and consulting firm GlobalData.

India's rapidly growing generics market is the primary driver of the nation's pharmaceutical sector, with sales expected to soar by nearly 84 percent to $ 26.1 billion in 2016. Generic drugs, with their low costs and easy accessibility, now dominate India's pharmaceutical space, accounting for around 70 percent of the market.

8. **India Can Become A World Leader In Affordable Health Care: PM Modi** – NDTV
   The Centre is committed to promoting traditional medicinal systems like Ayurveda which remain untapped due to inadequate scientific scrutiny and concerns regarding standards and quality, Prime Minister Narendra Modi said today.

   PM Modi said India would learn from the experience of other countries, especially China, which has put in place policies and regulations for promoting their traditional medicine and said the country can become a world leader in affordable and holistic healthcare.

9. **Sun Pharma, Lupin launch generics in US** – Business Standard
   Sun Pharmaceuticals and Lupin have launched the generic versions of top selling drugs with 180 days' sale exclusivity in the US market.

   The product launches will give a boost to the US business of the two companies, which have been hit by fewer approvals as well as regulatory compliance issues. Both the firms reported a drop in revenue from the US market in the second quarter of FY16. For the two companies, the US market accounts for 40-50 per cent of the total revenue.

   Also appeared in The Economic Times

10. **Aurobindo gets USFDA nod for arthritis drug** – Business Standard
    Aurobindo Pharma has received final approval from the US Food and Drug Administration (US FDA) to manufacture and market Celecoxib capsules. These capsules are used in the treatment of pain and inflammation of osteoarthritis, rheumatoid arthritis among others.

    The approved product has an estimated market size of $ 976 million for twelve months ending November 2015, according to a company press release.

11. **Article on the Internet of Things - Towards smarter healthcare** – The Hindu
    For all the attention the Internet of Things has received over the past year, one aspect has hardly been spoken about - how this emerging tech holds the potential of revolutionising healthcare by improving access and lowering costs. Whether it's allowing rural clinics to afford medical devices so far seen only in big city hospitals, to health tracking that allows chronically ill people to lead fulfilling lives, this new field of technology will soon be seen impacting our quality of life in a meaningful way.