1. New Year, new requirements- Cos stare at high compliance costs with new laws – The Economic Times

Legal and regulatory compliance may prove to be one of the biggest challenges for India Inc in 2017 when a slew of legislations including the goods and services tax (GST), Insolvency Code, and Benami Amendment Act come into force. Sectors such as real estate, automobiles, banking and pharma would be the most impacted with the regulations kicking in to bring about structural shifts.

The pharmaceutical industry has historically borne higher than average cost of regulations due to its high exposure to regulated markets. With increased scrutiny by the US Food and Drug Administration (FDA) accompanied by price control regulations enforced by the Indian government, top companies' legal costs have quadrupled in the past five years.The top five drug makers in the country spent nearly Rs 3,500 crore in legal costs in 2015-16.

"Indian pharma companies are taking regulatory risks emanating from US FDA, US Foreign Corrupt Practices Act and Indian government's Uniform Code of Pharmaceutical Marketing Ethics very seriously," said Sujay Shetty, pharma leader at PwC India. "This is especially critical given the issues in China that took place a couple of years ago. Another reason is the tightening of scrutiny by US FDA on Indian plants and Indian government's moves to tighten up selling practices," he said.

2. Outlook for pharma, education and microfinance in 2017 – Business Today

What can the Indian pharma companies hope to look forward to in the new year? After all, market headwinds in the form of drug pricing pressures, both in India and the US, and regulatory compliance issues are expected to continue even in 2017. Some of the industry veterans feel a greater focus on smart portfolio choices will get even more critical in 2017.

This, they say, is crucial in the context of the factors that characterized 2016. For the year just concluded stood out for the noise around regulatory hurdles and price control pressures. In the Indian market, the moves by the government around bringing in price control, be it for essential medicines or for medical devices like stents, was loud and clear. The drug pricing pressures were an equal concern if not more, for Indian companies operating in their biggest global market, the

United States of America. The presidential election campaign put medicine pricing as an important area for concern.

3. **Health ministry notifies EHR standards 2016 – Press Trust of India**
The Union Health Ministry has notified the Electronic Health Records (EHR) standards 2016 with an aim to introduce a uniform system for creation and maintenance of health records by healthcare providers. The health ministry said the idea that any person in the country can go to any healthcare provider, medical practitioner or pharmacy and access fully integrated health records in electronic format is the vision for "efficient" 21st century healthcare delivery. "With an objective to introduce a uniform standard based system for creation and maintenance of EHRs by healthcare providers, the Health Ministry notified EHR standards for India in 2013. "With passage of time, EHR standards 2013 have been duly revised in line with contemporary developments in consultation with stakeholders. Accordingly, EHR standards 2016 document is notified and placed for adoption in IT systems by healthcare institutions and providers across the country," a circular by the ministry said.

4. **NPPA's mobile app: When consumers can get the price right on medicines – The Hindu Business Line**
It's been four months since the National Pharmaceutical Pricing Authority (NPPA) rolled out its "Pharma Sahi Daam' mobile app. Having got around its initial teething problems, the app will soon be accessible to iPhone users as well. There have been 30,000 downloads since the app was launched in late August and the iOS version will be available by January 15, NPPA Chairman Bhupendra Singh told BusinessLine. The experience over the last few months has been that customers have come back to the authorities with feedback and complaints on the prices, he added.

5. **Pharmaceutical sector: 4-5 per cent drugs substandard, need concerted effort and stern action – The Indian Express**
Three to five per cent of the drugs in the Indian market are still substandard and the central drug regulator and state regulators would require to put in "concerted effort" and take "stern actions" to deal with it, stated G N Singh, Drug Controller General of India (DCGI), in his letter to all state drug regulators on December 30. "Although the menace of spurious drugs has reduced over the years, the percentage of Not of Standard Quality drugs reported in the country are still hovering around 4-5 per cent…Therefore, I solicit your sincere cooperation for making a concerted effort to reduce to a great extent the occurrence of substandard and spurious drugs even if it requires stern actions" G N Singh noted.

6. **Prices of stents likely to be capped – The Hindu**
In a relief to patients suffering from coronary artery blockages, the National Pharmaceutical Pricing Authority has invited all stakeholders to discuss capping of prices of stents at a three-day summit in New Delhi from January 4 to 6. While fixing the ceiling price may help bring down exorbitant costs of stents, some stakeholders fear that companies will stop selling new generation products if the ceiling is reduced drastically. The NPPA has invited representatives from medical devices manufacturing companies, chambers of commerce representing the medical devices sector, hospitals and nursing homes, eminent cardiologists, medical devices distributors, civil society associations and non-government organisations to put forward their suggestions at the meeting.

7. **Boosting healthcare in rural, tribal dists: Maharashtra Govt to set up 111 hospitals, health centres – The Indian Express**
In a bid to improve healthcare infrastructure, the state government is set to start 111 hospitals and health centres, mostly in rural and tribal districts of Maharashtra. In the next three months, four women's hospitals, two district hospitals, three sub-district, one rural, six trauma-care hospitals and

20 public health centres along with 74 sub-centres will be kick-started. With the healthcare burden falling on Mumbai's tertiary care hospitals, the government is pushing for easy access to medical facilities in rural belts like Nandurbar, Chandrapur and Gadchiroli, where 100-bed women's hospitals will be set up to curb the maternal mortality rate along with new PHCs. A regional referral hospital is also being developed in Amravati to provide specialised services and surgeries.

8. **New drug approvals fall to six-year low in 2016 – Reuters.com**
Last year turned out to be a disappointing one for new drug approvals with the U.S. Food and Drug Administration clearing just 22 new medicines for sale, the lowest number since 2010 and sharply down on 2015's tally of 45. Across the Atlantic, the European Medicines Agency recommended 81 new prescription products against a 2015 total of 93. Unlike the FDA, the EMA includes generic drugs in its list. The slowdown suggests the pharmaceuticals industry may be returning to more normal productivity levels after a spike in approvals in 2014 and 2015, when the haul of new drugs reaching the market hit a 19-year high. Several factors led to the fall in the approval rate in 2016, John Jenkins, the FDA's director of the office of new drugs, told a conference last month.

9. **Natco Pharma unveils generic version of Hepatitis C drug in Nepal – The Hindu Business Line**
Natco Pharma today announced the launch of the first generic version of Sofosbuvir 400mg/Velpatasvir 100 mg fixed dose combination in Nepal. Sofosbuvir 400mg/Velpatasvir 100 mg fixed dose combination is sold by Gilead Sciences, Inc., under the brandname Epclusa®. Epclusa® is the first all-oral, pan-genotypic, single tablet regimen for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection. The Hyderabad-based firm has priced its generic medicine of 'Velpanat' at ₹25,000 equivalent for a bottle of 28 tablets in Nepal. Natco has signed a non-exclusive licensing agreement with Gilead Sciences to manufacture and sell generic versions of its Hep C medicines in 101 developing countries.

Similar reports –
- Natco launches generic Hepatitis C drug Velpanat in Nepal – Business Standard
- NRK/Natco Pharma launches Hepatitis C drug in Nepal – The Hindu
- Natco Pharma gains on launching generic version of Sofosbuvir, Velpanat in Nepal – Mint

10. **State FDA receives renewal approvals for 33 blood banks out of 59 from DCGI – Pharmabiz.com**
Based on inspections carried across 59 blood banks licenses of which were due for renewals on December 31, 2016, the Maharashtra Food and Drug Administration (FDA) has received approvals for license renewal for 33 blood banks from the Drug Controller General of India (DCGI). This is a major boost to the blood banks in Maharashtra as the approvals for renewals have been received much before the expiry of licenses. Renewals for civic run blood banks at LTMG Hospital, Sion, KEM Hospital, Parel, St George hospital blood bank, JJ Hospital blood bank, Nair hospital blood bank, Bombay hospital blood bank, Breach Candy hospital blood bank, Lilavati Hospital, Bandra and Rajawadi Hospital, Ghatkopar have been approved by the DCGI among others.

As per the Drugs and Cosmetics Rules, 1945, blood bank licenses are valid for five years. Central licensing approving authority of Central Drugs Standard Control Organisation (CDSCO) renews licences after the state Food and Drug Administration (FDA) satisfies and recommends the same for renewal. Inspections rule out the errors on the part of the blood banks such as shortage of doctors, unavailability of kits to test antibodies or other equipment related issues.