1. **Pharma sector expects a sweet pill from budget 2017 – Business Standard**

The Indian pharma industry is a very dynamic sector and has witnessed tremendous growth as well as challenges over the last few years. This industry is expected to outperform the global pharma industry given the increasing health awareness, higher incidence of lifestyle diseases and booming healthcare insurance sector. In light of such anticipated growth rates, it is imperative that the pharma sector gets the necessary fillip on the income-tax front in the eagerly awaited union budget 2017.

As R&D is crucial to put India on the growth trajectory, it is important that the sunset date of 31 March 2020 applicable to in-house R&D facility to claim weighted deduction is either omitted or extended. Likewise, the cap of weighted deduction should also be restored to 200 percent as against 150 percent introduced in the 2016 budget.

2. **Rare diseases; orphan drugs – Mint**

In 2013, the Delhi high court heard a petition by Mohammed Ahmed, the seven-year-old son of a rickshaw-puller afflicted with Gaucher disease, a hereditary disorder caused by the absence of an enzyme that breaks down fat. Without this enzyme, fat builds up all over the body, resulting in bone pain, anaemia and eventually death. Mohammed can never be completely cured but with enzyme replacement therapy, he can live as close to a normal life as possible. Unfortunately, the therapy costs Rs6 lakh a dose, and must be administered once a month, every month for the rest of his life. This was well beyond the financial resources of his family and the petition to the high court was a plea for help. Gaucher is one of about 7,000 “rare” diseases that afflict less than 6% of the global population. Given the low volumes at which the drugs needed to treat such diseases would be consumed, pharmaceutical companies have little commercial incentive to produce them.

3. **Stent-makers asked to disclose price data – The Times of India**

In a move intended to make it difficult for stent makers to flout price caps soon to be notified by the government, the drug price regulator has made it mandatory for companies to disclose detailed pricing data and information about their products by January 31. As it moves to finalise price control mechanism for stents, the National Pharmaceutical Pricing Authority (NPPA) has asked for disclosure of such data to bring in more transparency and clarity in coronary stent pricing. In a notification issued on Tuesday, NPPA has directed all stent manufacturers, marketers and importers to submit

detailed pricing data related to maximum retail price (MRP) as well as price charged to distributors, stockists, hospitals and retailers. "Companies will have to update this information regularly," an official said. Any company not submitting such information will attract action from the regulator under the Drug Price Control Order, 2013, NPPA said. The move is aimed at curbing profiteering and opening the economics of manufacturing and retailing of stents to public scrutiny.

4. **Pharma sector to witness another muted quarter; US business to stay in focus – The Financial Express**
   We expect another muted quarter for the pharma sector led by weakness in US business. USFDA inspections and pricing in US market will continue to dominate the results. Recent comments from global peers have indicated that pricing scenario will likely remain unchanged in 2017. We expect Aurobindo and Natco to report strong results while DRRD reports muted results. Another muted quarter: We expect Indian pharma to report revenue growth of 12% and margin decline of 100 bps y-o-y. US business will remain the key focus given regulatory and pricing headwinds. In India, we expect limited impact from de-monetisation for pharma. FDA inspections to remain in focus: Given the re-emerged FDA headwinds for select companies, we expect FDA inspections to remain in focus especially for companies under warning letters. We expect DRRD and CDH to see inspection in the near-term. Additionally, we will look for commentary from SUNP on Halol resolution.

5. **No more misuse of drugs: Arbitrary sale of antibiotics under scanner – Business Standard**
   Reports that an American woman visiting the country died after being infected by a super bug are making the Indian authorities sit up. Since the case is being linked to developing resistance to all antibiotics, the Centre is in talks with state governments to go tough on any misuse of such drugs. Drugs Controller General of India G N Singh told Business Standard that an advisory is being issued to all state drug controllers asking them to crack the whip on arbitrary sale of antibiotics. The state controllers would help ensure that no chemist in India sells antibiotics without a valid prescription, Singh said. Even the least powerful antibiotics can prove fatal if taken more than the prescribed dosage, according to the DCGI. Misuse of antibiotics can also lead to antimicrobial resistance, he said while explaining why preventing people from taking unnecessary doses of antibiotics is essential.

6. **Hospitals make a killing on stents: NPPA – The Hindu Business Line**
   Hospitals are taking the scalpel to patient's hearts and pockets, a document shared by the National Pharmaceutical Pricing Authority reveals. It shows a staggering increase in prices of stents with hospitals enjoying unimaginably high trade margins — as much as 654 per cent. The Authority, which has proposed several different pricing mechanisms as the essential devices are set to come under price control, shared a document comparing the minimum and maximum prices at different stages — landed cost, price to distributor, price to hospitals and retail prices — for imported and domestic bare metal and drug eluting stents. The data show that the prices of imported bare metal stents with landed cost between ₹4,192 and ₹16,749 would finally cost the patient and his family anywhere between ₹30,000 and ₹50,000. The price differences for domestic bare metal stents also fall in the same range — finally weighing in at ₹25,000 to ₹75,000 for the patient.

7. **Superbug-related death spurs drug regulator warning – The Times of India**
   In the wake of the recent death of an American woman after contracting an infection resistant to antibiotics, the drug regulator has directed the pharma supply chain, including retailers, chemists and drug makers, to strictly follow norms while selling antibiotics. The Drugs Controller General of India (DCGI) has also asked companies to carry specified warnings to avoid antimicrobial resistance. "To contain anti-microbial resistance, the office has been advising the supply chain system in India to follow strict requirements of Schedule H and H1 for sale of medicines," DCGI GN Singh said in a notice issued to all state regulators and other stakeholders. The Centre has also asked state drug regulators to take "strong policy measures including stringent regulatory action on the over-the-counter (without prescription) sale of high-end antibiotics".

8. **Budget should encourage indigenous innovation: Dr K M Cherian – Business Standard**
   For this budget, I hope the central government would address a fundamental challenge in our healthcare system, which has to be addressed at a policy level. India depends upon import for more than 75 percent of medical device requirements and patented drugs, thus making healthcare unaffordable to the masses and losing precious foreign exchange. While we are big on generic drugs, new molecule development and patenting in the country is lacklustre. Data from World Intellectual Property Organisation (WIPO) shows that South Korea has 4,451 patent filing per 1 million population, Japan has 3,716 ad China has 541. Compared to these, India has 17! According to Scopus database, India has 4 researchers per 10,000 working people compared to 70 in the US, 58 in Russia, and 6 in Kenya. Nature magazine (May 2015 issue) reported that India's publications generate fewer citations than countries like Brazil and China. It also stated that many Indian born scientists choose to settle overseas.

9. **DoP finds NPPA's notification No.644(E) dated 2.3.2016 wrong in asking companies to further lower MRP than ceiling price fixed by NPPA – Pharmabiz.com**
   The Department of Pharmaceuticals (DoP) has found Note (e) of NPPA's Price Fixation Notification S.O. 644(E), dated 02.03.2016 wrong in asking the companies to further reduce the MRPs of their products which are lower than the respective ceiling prices on account of revision in Wholesale Price Index (WPI). Stating that the NPPA has clearly erred in inclusion of Note (e) in the SO dated 2.3.2016, the DoP noted that the companies already selling their scheduled formulations lower than the ceiling price may not be required to further lower the prices of their products by applicability of negative WPI as they are already well within the ceiling price fixed by NPPA in the light of new WPI. Earlier, the NPPA had issued price notification No. SO 644(E), dated 2nd March, 2016, revising the ceiling prices of scheduled formulations with negative WPI with effect from 1st April, 2016. Note (e) of the notification reads, "(e) All the manufacturers of above mentioned scheduled formulations (as contained in table in notification SO 644(E), dt.2.3.2016) having MRP lower than the ceiling price specified in column (5) in the above table (table in notification SO 644(E), dt.2.3.2016) plus local taxes as applicable, if any, shall make corresponding reduction in the maximum retail prices as per the provision of paragraph 16(4)."

10. **Change to IDA from CSDCO will usher in fresh wave of accountability & professionalism: Dr Jagashetty – Pharmabiz.com**
    The Drug Technical Advisory Board (DTAB)'s move to approve change of name of the 'Central Drugs Standards Control Organisation (CDSCO)' to 'Indian Drug Administration (IDA)' will now mandate a dedicated pool of qualified workforce to man regulatory system. This will take India on a global platform like that of US FDA and EMA, said Dr BR Jagashetty, former National Adviser (Drugs Control) to MoHFW & CDSCO. Following the 75th meeting of DTAB held on January 3, 2017, the Board's approval to rename 'CDSCO' as 'IDA' to make it simple and befitting to its activities is the best that could happen to India's regulatory office, he added. During 2014, it was Dr Jagashetty in his role as the National Advisor who pressed for the CDSCO to be transformed with a name change to IDA and be given a different identity for an immediate recognition as an Indian Regulatory Authority across the globe. "Now the IDA will lay the foundation for qualified pharmacy professionals and this will automatically spur rapid license approvals in a transparent and efficient manner," he said.