1. **Pfizer-Allergan deal a non-event for India** – Business Today

In the global media, it is being described as the biggest takeover deal in pharma that is expected to be officially announced on Monday. The New York Times for instance says: "Pfizer has clinched a blockbuster merger with a fellow drug maker, one worth more than $150 billion, that can best be described in superlatives."

But some of the leading analysts and pharma company executives in India tell Business Today that the deal is largely a non-event for Indian pharma companies.

First, it is a deal between innovators, and Indian companies are in the generics drugs business. Pfizer has its presence in India and Allergan, even less, and is really known for its ophthalmology products. One of its popular products in India is 'Refresh Tears,' an eye-lubricant. Globally, Allergan is also known the "Botox maker".

2. **Pfizer leaving US unsettles drug lobbyists** – Business Standard

Pharmaceutical giant Pfizer has long been the most politically active drug maker in Washington, and its representatives have tended to wrap themselves in the American flag while pressing their concerns with lawmakers and regulators. So when the company announced this week that it would abandon not only the flag but the United States, its planned move to Ireland stunned the medicine industry's lobbying corps - not the least because Pfizer's chief lobbyist, Sally Susman, is the daughter of one of President Obama's biggest, most generous benefactors, Louis Susman.

The lobbyists asked for anonymity since criticising Pfizer or the industry's present position in Washington could get them fired.

The pharmaceutical industry was once the world's most profitable, its companies topping lists of the world's most admired corporations and Washington's lists of its most influential. The industry has for years invested more in lobbying than any other.

3. **GlaxoSmithKline trying to escape the shadow of a bribing scandal in China** – The Economic Times

GlaxoSmithKline Plc has cut 40 per cent of its sales reps in China and axed some units as it eyes a return to growth in 2016, after sales plunged during a bribery scandal that landed it with a record $490 million fine in 2014.

The British firm is gambling on a new, cleaner image to reboot its performance and reputation with doctors and consumers, China head Herve Gisserot told Reuters during a wide-ranging interview at the group's Shanghai headquarters.

4. **Merck KGaA aims to put out a new drug every year -WirtschaftsWoche** – Reuters
Merck KGaA aims to bring to market one new drug every year from 2017 onward, starting with cancer treatment avelumab, incoming CEO Stefan Oschmann tells German weekly business magazine WirtschaftsWoche.

** Outgoing CEO Karl-Ludwig Kley says he won't join family holding E. Merck KG's board after leaving CEO post in April, according to WirtschaftsWoche

** "I will not join the board of partners. Not even after a two-year cooling-off period," the magazine quotes Kley as saying

** The Merck family holds 70 percent of the group

5. **Merck plans to sell its allergy business unit to cut debt: Reports** – The Economic Times
German drugs and chemicals maker Merck GaA is planning to sell its allergy business, Allergopharma, Bloomberg reported, citing sources.

The sale, which could fetch about 600 million euros, is an attempt by the company to offload its debt after the Sigma Aldrich Corp takeover, the multimedia news website said on Thursday. The company raised its full-year guidance for core earnings before one-offs, two weeks ago, to include the $17 billion acquisition of Sigma-Aldrich, which has cleared regulatory hurdles.

6. **Sunset clause for SEZs 'at odds' with Make in India: Dr Reddy's** – ET Health
Dr Reddy's Laboratories has said the Centre's decision to introduce sunset clause for Special Economic Zones (SEZs) from March 2017 is "at odds" with the Make in India objective and should be deferred.

Furthermore, the withdrawal of R&D weighted deduction is potentially counter-productive and likely to negatively impact India's innovation efforts, he opined. Countries across the world have been introducing various measures for promoting R&D initiatives in the form of credit, weighted deduction and patent box.

"The R&D weighted deduction must continue, to provide India a level-playing field in an increasingly competitive global innovation environment," said Saumen Chakroborty, President and CFO, Dr. Reddy.

7. **USFDA gives Dr Reddy's Laboratories additional time to respond to warning letter** – The Economic Times
Dr Reddy's Laboratories Ltd (DRL) today said the USFDA has extended the time-frame for replying to the warning letter issued to the company by about two weeks to December 7.

The company also said that it is in the process of preparing responses to the letter on November 5 by the US Food and Drug Administration. The FDA, which issued a warning letter to Dr Reddy's Laboratories on November 5 on three of its plants, said it found several violations with regard to current good manufacturing practices (CGMP).

The US regulator cautioned that it may withhold approval to any new drugs or Active Pharmaceutical Ingredients (API) and stop importing if the company "fails to correct the violations".

8. **Reviving pharma sector** – Pharmabiz.com
In November last year the Department of Pharmaceuticals had set up a Task Force on 'Enabling the Private Sector to lead the growth of Pharmaceutical Sector' headed by its secretary to provide

a big thrust to the ailing pharmaceutical industry of the country. The other members of the task force are from Planning Commission, Department of Industrial Policy and Promotion, Department of science and technology, Department of biotechnology and various industry associations. After achieving a commendable growth for almost 25 years, Indian pharmaceutical industry has been facing tough times from 2010 on account of various internal and external factors. This was getting reflected in the overall sales and profitability of many top Indian companies since then. As the profit growth of most of the Indian companies depended on the exports to the developed countries and mainly to the US, repeated actions against Indian manufacturing facilities by the US FDA on regulatory issues have been affecting exports quite seriously. And it is a fact that the frequency of regulatory inspections of manufacturing facilities of Indian companies has been stepped up by the US FDA in recent years. Now the question remains whether Indian companies have been taking adequate care in maintaining good manufacturing practices in their facilities and the product quality or is it a deliberate attempt by the US authorities to check the steadily growing pharmaceutical export from India to the US.

9. **Health ministry to amend D&C Rules to exempt clinical trials for academic research from DCGI nod** – Pharmbiz.com
   The Union health ministry will soon amend the Drugs and Cosmetics Rules, 1945 for providing exemption in the case of clinical trials undertaken in the medical institutions or hospitals for academic research. Once the amendment is done, these institutions and hospitals do not have to take the now mandatory prior permission from the Drugs Controller General of India (DCGI).

   According to sources, the Drugs Technical Advisory Board (DTAB), the highest authority under the Union health ministry on technical matters, in its 70th meeting held on August 18, 2015, has given its approval for a proposal by the ministry in this regard.