1. **Many cancer drugs have generic versions in the market** – ET Health

The main criteria for inclusion of a medicine in the NLEM is those which are used for public health, and also be comparatively cost effective.

Though many of the cancer and HIV drugs on which exemptions have been withdrawn have generic versions in the market, there will be a price impact on both imported and indigenously produced drugs between 10-25%, Biocon chairperson and MD Kiran Mazumdar-Shaw told TOI, adding, this will only impact patients.The medicines on which customs duty will now be imposed include the ones used for treating kidney stones, chemotherapy and radiotherapy, life-threatening heart rhythm disorders, Parkinson's disease, bone diseases, antibiotic to treat infections, leukemia, allergies, arthritis and lupus.

When contacted, Ranjit Shahani, Novartis India VC and MD said "This move is not in the interest of patients. The government should be directionally moving towards a 0% regime for life-saving drugs".

2. **Customs blow to make life-saving drugs costlier Customs blow to make life-saving drugs costlier** – The Times of India

The Centre's recent tweak in levies — removing customs duty waiver as well as imposing excise duty on certain lifesaving drugs including for cancer, HIV, haemophilia, diabetes and infections may result in price increases between 10-25% on both imported and indigenously-produced drugs, swelling treatment costs and restricting key drugs for patients.

Organisation of Pharmaceutical Producers of India, which represents MNC firms' interests, believes the recent hike in duties on lifesaving drugs will be detrimental to patients, and may also have a significant impact on companies' patient access programmes.

3. **Withdrawing customs duty may lead to hike in medicine prices: DG Shah** – The Economic Times
The government's move to withdraw customs duty exemption on imports of around 74 drugs would help in local production of bulk drugs and thereby create demand for the local production but it may also lead to rise in prices for these medicines. According to Indian Pharmaceutical Alliance Secretary General D G Shah, the recommendation to prune the lists was aimed mainly at taking stock of the current status of the industry and to rationalise the exemptions.

"It also aimed at promoting the local production of bulk drugs and reduce dependence on cheap imports from China. It is thus aligned with the overall objective of reviving the bulk drug industry in the country," Shah told PTI.

On the other hand, Organisation of Pharmaceutical Producers of India Director General Ranjana Smetacek told PTI that the industry body was not consulted on this and "we believe the recent hike in duties on life saving drugs will be detrimental to Indian patients."

4. **Cust duty exemption withdrawal on life saving drugs face flak** – Business Standard
The withdrawal of customs duty exemption on imports of life-saving drugs came under criticism today with Biocon chief Kiran Mazumdar-Shaw saying levy of any kind of duty for these medicines does not resonate well with India's affordable healthcare mission.

Echoing Mazumdar-Shaw's view, the Organisation of Pharmaceutical Producers of India Director General Ranjana Smetacek told PTI the government move will be detrimental to Indian patients depending on life-saving drugs.

Also appeared in Hindustan Times, The Hindu, The Hindu Business Line

5. **The pill that costs $9,000 in US sells for $70 in India** – The Times of India
   - India's generic industry has been producing many such life-saving medicines at a fraction of the global price
   - Country's generic medicines are a lifeline for millions not only in low and middle-income countries but also in the developed world

And that's just one leukaemia drug. India's generic industry has been producing many such life-saving medicines at a fraction of the global price. Last month, generic manufacturer Natco announced that it would be supplying daclatasvir, a Hepatitis C drug, to 112 developing countries. In 2013, a medicine to treat hepatitis C, sofosbuvir, hit international headlines for its price -$1,000 per pill. Gram for gram, it cost 67 times the price of gold. The sofosbuivir and daclatasvir combination used for the disease costs almost $150,000 per patient for the 12-week regimen in the US. But in India, it is priced at just $700 or a little over Rs 46,500 per patient for the same regimen. And prices are expected to fall further. So how does the Indian generic industry manage to do it? The patent law in India is stringent on what is innovative enough to get a patent. Plus, the crucial section 3(d) in the law, much criticized by multinationals, has prevented "evergreening" -the attempt to patent different aspects and improvements of the same drug to extend the period of patent -a lucrative game for the pharmaceutical business.

India's patent law also provides for granting of compulsory licences -under which the government can give a licence to a manufacturer other than the patent holder for a royalty fixed by it -for public health reasons. This can be used where drugs are unavailable or unaffordable. The only compulsory licence granted was in 2012 when the patent office allowed the Indian generic company Natco to market sorafenib, a drug patented by Bayer to treat kidney and liver cancer.This move, upheld by the Supreme Court in December 2014 helped bring down the price by 97%, unimaginable through a price negotiation with the company .

6. **EU refuses to budge on GVK Bio case, closes talks** – The Hindu Business Line
The Centre's six-month-long negotiations with the European Union for revoking a ban on drugs based on clinical trials conducted by GVK Biosciences appears to have come to a nought.

At a recent meeting with a team from the Commerce Ministry, the EU conveyed its unwillingness to reconsider its decision, a senior Indian official said. "Despite the best efforts of the government, they (EU) remain unconvinced and also are reluctant to pursue the matter further," he told BusinessLine.

In July 2015, the EU banned 700 generics (versions of off-patent drugs) tested by Hyderabad-based GVK Biosciences, following charges of manipulation of clinical trials for bio-equivalence testing by French standards agency ANSM.

7. **Editorial: Unfair trade** – The Hindu Business Line
The European Union's recent change in its trademark legislation, which has provisions that could potentially confiscate shipments of Indian medicines to other destinations via European ports or airports, smacks of another attempt by European drug companies to check Indian generics. This is not the first time the EU has used non-tariff measures to protect the interests of its domestic lobbies. Last year, it used some minor discrepancies in lab tests as a handle to ban over 700 generic formulations manufactured by GVK Biosciences — a move India viewed as an attempt to choke India's $15-billion generic pharmaceuticals sector, and led to the talks on the proposed India-EU free trade agreement being called off. While EU authorities have argued that the changes to the trademark rules were "unlikely" to lead to confiscation, India has good grounds to be wary. Between 2009 and 2011, EU customs authorities confiscated several Indian off-patent generic drug consignments going to Brazil via European ports and airports, over alleged infringement of EU intellectual property rights (IPR). India, together with Brazil, filed a case against the EU in the World Trade Organisation protesting the action. India argued that such seizures were against the multilateral Trade Related Intellectual Property Rights (TRIPS) agreement, as the medicines were off-patent both in India and the country to which they were being exported. In 2011, the EU reached an understanding with India under which it would no longer seize Indian drug consignments in transit to other countries for IPR violation.

8. **Dependence on imported APIs is worrisome: Nirmala Sitharaman** – The Economic Times
Commerce and industry Minister Nirmala Sitharaman today raised serious concerns over increasing imports of active pharmaceutical ingredients (APIs) and asked the experts and industry to work in the direction to reduce the dependence on imports.

"When we are setting up pharmaceutical and biotechnology hubs... the dependence on imported APIs worries me a lot," she said here at the Global Biotechnology Summit here.

The minister said both developing and developed countries are dependent on India for affordable generic medicines.

9. **India flags API issue to U.S. govt.** – The Hindu
Medicines need to be made in the U.S., or in certain 'designated countries,' as per U.S. trade rules

India has sought clarity from the U.S. government on the ramifications of a recent adjudication, which gave rise to apprehensions that the medicines procured by the American government should be only from companies making even the Active Pharmaceutical Ingredients (API) either locally or in certain designated nations such as European Union (EU) members.

India and China account for about 80 per cent of the U.S.'s requirement of API (drug raw materials). The 'determination' of the U.S. Homeland Security Department — which seemed to imply that the drugs that contained APIs imported from India and China are ineligible to be sold to the U.S. government — is likely to directly and indirectly hurt India's API exports to the U.S., according to a preliminary assessment by India's commerce ministry.

"India has flagged the issue to the U.S. at the highest level, as it is of concern to us," a senior government official told The Hindu on condition of anonymity. "The U.S. decision has major implications on generic drugs, affordability of medicines and on efficient sourcing." An inter-ministerial meeting will be held shortly to assess the impact of the U.S. move.

10. **Doctors who take gifts from pharma firms to be punished: MCI guidelines** – The Indian Express
DOCTORS accepting freebies such as gifts and foreign jaunts from pharmaceutical companies will now be punished, based on the value of gifts received. The punishment will range from a censure for gifts of up to Rs 5,000 to deletion of the errant doctor's name from the state or national medical register for a period of one year or more for freebies valued more than Rs 1 lakh. The Medical Council of India (MCI) is set to notify the new ethical guidelines under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2015. For the first time, these guidelines will define punishment for errant doctors based on the value of favours or freebies received from pharma companies.

    While the Indian Medical Council Regulations, 2009 bar doctors from receiving freebies, the punishment, if caught, is now subject to the discretion of either the central or the state councils' ethics committee. A voluntary code of conduct for pharmaceutical companies came into effect from January 2015. It was to be reviewed a few months later to decide whether it should instead be made mandatory. The review is still pending.

11. **Insulin out of reach for millions of diabetics globally: Study** – The Times of India
More than 90 years after its discovery, insulin, which is essential to treat type 1 diabetes, remains unattainable to many globally due to high prices and manufacturing constraints, according to a new study published in The Lancet.

    According to the study, a possible reason behind constant escalation in price of insulin may be the domination of insulin manufacturing by three multinational companies, which control 99% of the global insulin market in terms of value and 96% in terms of volume. Experts say that to address the issue of access to insulin there is a need to set up a 'prequalification scheme' by World Health Organization. The scheme is already in place for drugs used to treat HIV, malaria and tuberculosis. The prequalification scheme allows countries to know whether manufacturers meet the required standards for good manufacturing practices and provides assurances on the quality and efficacy of the products.

12. **Don't politicise TPP, China tells U.S.** – The Hindu
China has warned the United States not to politicise international trade following comments by President Barack Obama as the Trans-Pacific Partnership (TPP), a U.S.-led free trade deal in the Asia-Pacific that excludes Beijing, was signed.

    China's Foreign Ministry spokesman Lu Kang on Friday urged relevant countries and governments "not to politicise economic and trade issues", and avoid leading people to the conclusion that the U.S. has been promoting the TPP "out of certain political consideration".

13. **Glenmark introduces EMI scheme for cancer treatment drugs** – The Economic Times
Glenmark Pharmaceuticals has rolled out an EMI scheme for cancer patients in order to help them continue the treatment and meet the high cost of medication.

    The Mumbai-based company has included its two drugs -- Abirapro prescribed for prostate cancer and Evermil, indicated for different cancers, such as breast and renal cell carcinoma -- under the scheme.

14. **Pharma cos to see muted exports, stable revenues in FY17: Report** – The Economic Times
The pharmaceutical industry is expected to register muted export revenue growth and stable domestic revenue increase in 2016-17, a report said.

The overall pharmaceutical exports are expected to grow at about 5 per cent, while domestic pharma market is likely to grow at 8-10 per cent in the next fiscal.

"The recent increase in US regulatory actions against domestic pharmaceutical companies is likely to restrict growth of exports to the US.

15. Cancer cure rates better, but new cases on the rise too**Tamil Nadu, star performer in healthcare, slows down** – The Times of India
Once a trail-blazer in the field of healthcare, Tamil Nadu has slipped in a range of deliverables, including services for women and child health. One of the biggest slips has been with regard to the maternal mortality ratio. Sample registration system data, released by census, shows that until 2009 Tamil Nadu held the second position in the country with 97 women deaths per 10,000 live births.Every year since then the numbers dropped but Tamil Nadu's drop was not as big as the others. In 2010, there were 87 women deaths per 10,000 live births in Maharashtra and 90 in TN. Between 2011 and 13, the gap between the two states widened by 11.

16. **Pharmacies Get the Right Dose** – The New Indian Express (Sunday Standard)
Unhappy with the performance of the 'Jan Aushadhi' scheme, the government is all set to relaunch a new-look generic drugs programme on February 15 renaming it as the 'Pradhan Mantri Jan Aushadhi Yojana (PMJAY)'.

    The speeding up of the process of revamping and relaunching the scheme comes after direct interest shown by the Prime Minister's Office. The 'Jan Aushadhi' scheme aims to make available quality medicines at affordable prices for all, especially the poor.

17. **Biocon set to seek USFDA approval for biosimilars** – The Indian Express
India's largest biopharma company, Biocon, is gearing up to enter the regulated markets of the US and the UK with a portfolio of biosimilars. The company is in advanced stages of completing global phase-III trials for four out of nine biosimilar programmes in partnership with Mylan, a US-based drug maker. "Based on the clinical advancement thus far, the Biocon-Mylan biosimilars partnership is progressing well towards four regulatory filings in the US and EU in this calendar year," Kiran Mazumdar-Shaw, chairperson and MD of Biocon, said.

18. **Don't buy medicines online: FDA to citizens** – DNA
In a move to control the rising popularity of online sale of drugs, the food and drugs administration (FDA) has appealed to the citizens to avoid purchasing medicines online as it is an unregulated area and quality of drug sold isn't monitored.

    The FDA said that since the government is still in process of how to monitor and regulate online sale of drugs, they cannot presently take action on people selling medicines online.