1. **Withdrawal of duty cuts: who is affected and by how much** – The Indian Express

Last month's notification laid down categories in which current Customs duty exemptions were to continue. Sixty-one bulk drugs and 15 formulations were removed from the list — including imported and locally manufactured drugs; drugs marketed both by companies that hold the patents for the molecules, and those that manufacture generic versions. All 76 drugs will now be subject to normal rates of basic duty at 7.5% and countervailing duty at 12.5%. Currently, 15 of the 76 items attract 0% duty, others 5%.

In the pharma industry, there is duty on the raw material and exemption in the finished product amounting to the same tax that was paid on the raw material. However the actual price rise post exemption will be a function, among other things, of the selling price of the drug. This would mean MNCs that hold patents for certain life-saving drugs, and usually sell them for far more, would be at a disadvantage — because after the withdrawal of exemption, the absolute amount by which the price would have to be increased would be more for them. Local companies will suffer a smaller increase. Almost all drugs now off the list are also manufactured by local companies. For example, Glivec, for which Novartis holds the patent everywhere except India, is available in its generic avatar as Imatinib mesylate, and is manufactured by six Indian companies. It has by and large welcomed the move, saying it would encourage local manufacturers and reduce India's dependence on Chinese bulk drugs imports. In October last year, the Indian Drug Manufacturers' Association had lobbied for a removal of duty exemptions to provide a "level playing field" to Indian companies.

2. **Essential medicines list: Stents may take the place of condoms** – Mint

Will the coronary stent take the place of the condom in the list of essential medicines?

The answer lies in an upcoming report that will recommend what all should go into the national list of essential medicines (NLEM), a list from which the Delhi high court struck out condoms last year.

While manufacturers hope that stents will be kept out of the list, patients will have to pay more for these tiny expandable tubes that open up narrowed or weakened arteries to prevent chest pains and reduce chances of a cardiac arrest.

3. **Biocon gets nod to sell generic Crestor in Europe** – The Times of India
   Biopharmaceutical company Biocon said it received approval to sell the generic version of AstraZeneca's top-selling cholesterol drug, Crestor, in the European Union.

   AstraZeneca, which saw off a takeover attempt by Pfizer two years ago, warned earlier this month of profit drops this year hurt by the patent expiry of Crestor in the US.

   Also appeared in Mint, The Hindu Business Line

4. **IDMA strongly reacts to report on price rise of 76 lifesaving drugs** – Express Pharma
   Indian Drug Manufacturers' Association (IDMA) has reacted to the recent reports on the price of lifesaving drugs, where it was stated that the price of 76 life saving drugs will go up due to the recent customs notification. IDMA's release states that the statements made in these news reports are not representative of the pharmaceutical industry as a whole.

   SV Veerramani, National President, IDMA, said, "We have scrutinised the 76 Drugs mentioned in the above said notification for removal of NIL / Concessional duties and we understand that they have been selected by Government of India on the basis of availability of local manufacturing facilities. This being the case, providing customs duty exemption to this class of imported bulk drugs is not required."

5. **India drug monitoring program struggles to grow fast enough** – Reuters
   India's six-year-old pharmacovigilance program, which collects and submits suspected adverse drug reactions to a World Health Organization (WHO) database, is key to improving drug safety in a country where medicine consumption is high, experts say.

   Gaps in the system mean the government has less data to determine whether drugs might have harmful side effects. Also, relatively little information flows from one of the world's largest pharmaceutical markets to the WHO database of over 12 million suspected adverse drug reactions.
   To make a new drug in India, companies need permission from the national drug controller after submitting safety and efficacy data including from local clinical trials. For four years after an approved drug is on the market, firms must submit safety reports, including those on adverse drug reactions.

6. **US Pharmacopeia plans mechanism to monitor quality of Indian medicines** – Mint
   US Pharmacopeia (USP), the non-profit public standards-setting organization for medicines, dietary supplements and foods sold in the US and consumed worldwide, said on Monday that it was planning to launch a new system to generate data about the quality of medicines in India to help policymakers make a strong case for investment in quality.

   As of now, USP does not have much data on India, chief executive officer Ronald T. Piervincenzi said.
   USP opened its first office and collaborative laboratory facility outside of the US near Hyderabad in 2005 to help its work of developing and updating quality standards for medicines.

7. **US FDA calls for uniform drug global regulatory norms** – The Hindu Business Line
   There is a need for uniform regulatory standards for drugs across the globe, according to Mathew Thomas, Director, US Food and Drug Administration (USFDA), India.

   He was speaking at an event organised as part of the 10th anniversary of US Pharmacopeial Convention (USP) here recently.

   Referring to divergence in regulatory standards among the countries, he said there should be same standards of drug quality. This will help the industry as well the regulatory agencies. About 40 per cent of generic drugs from India are exported to the US.

8. **USFDA finds data manipulation, norm violations at 3 Ipca plants** – Business Standard
   The US health watchdog FDA in its observation has found major anomalies – including systemic data manipulation and manufacturing norm violations – at the three plants of Ipca Laboratories.

   According to the warning letter sent by the USFDA over the three plants, its inspectors observed systemic data manipulation and other current good manufacturing practices violations and deviations at the company's three facilities.

9. **1 In 7 Indian drugs revealed as sub-standard** – ABP Live
   Substandard medicines could be three times more prevalent than the government says, two new studies show.

   These data have serious implications on health in a country where 58.2 percent of the total health expenditure is an out-of-pocket cost burden on people, according to the World Health Organization, and where medicines alone account for between 70 percent and 77 percent of health spending.

   Substandard drugs work less effectively, causing disease to run a longer course, and can even require a new prescription during treatment. Substandard drugs also contribute to antibacterial resistance, a threat that has doubled in the last five years in India, IndiaSpend reported earlier.

   About 4.5 percent of the drugs in the Indian market are substandard, according to surveys by the Central Drug Standard Control Organisation (CDSCO), the official regulatory authority.