1. NPPA fixes price of 27 drug formulation packs – Mint
2. News in Numbers| Cancer burden in North – Eastern states highest in the world – Mint
3. USFDA to share details of rejected exports with India – Hindu Business Line
4. These were tough pills to swallow – Hindu Business Line
5. New IPR policy aims for 'Creative India: Innovative India' but few kinks remain – Financial Express
6. Drawing the red line for drug-resistant bugs – The Hindu
7. NPPA decision to cut post-surgical drug prices big relief for transplant patients – DNA
8. TB patients protest outside health ministry, promised proper drug regimes from July – DNA
9. Clinical trials must to curb rare diseases – Deccan Herald
10. A brighter future for clinical research in India – Express Pharma

1. **NPPA fixes price of 27 drug formulation packs** – Mint

Drug formulation packs whose ceiling price was fixed by the National Pharmaceutical Pricing Authority including those used for the treatment of bacterial infections, diabetes and epilepsy, among others. "NPPA has fixed/revised ceiling prices of 27 scheduled formulations of Schedule-I under Drugs (Price Control) Amendment Order, 2016 and and retail price of four formulations under the Drug (Price Control) Order, 2013," the NPPA said in a statement. The government had notified the DPCO, 2013, which covers 680 formulations, with effect from 15 May 2014, replacing the 1995 order that regulated prices of only 74 bulk drugs.

Similar story in India Today: NPPA fixes price of 27 drug formulation packs

2. **News in Numbers| Cancer burden in North – Eastern states highest in the world** – Mint

The cancer burden is estimated to be 14.5 lakh new cases of cancer in 2016 and 17.3 lakh new cases in 2020.

271/100,000 - What is it? The age-adjusted incidence (AAR) of cancer among males in Aizawl district in Mizoram between 2012-14, according to the National Cancer Registry Programme.

Why is it important? This is the highest in India for males. Among females the incidence is the highest in Papum Pare district, Arunachal Pradesh with an AAR of 249. In fact, cancer burden in the North-Eastern states is among the highest in the world . Granular data like this would help the policy makers and the health specialists in devising intervention specific to a particular geography, thereby making it a more focussed-approach in dealing with cancer burden. The cancer burden is estimated to be 14.5 lakh new cases of cancer in 2016 and 17.3 lakh new cases in 2020, with breast, lung and cervix as the leading types of the disease. The use of tobacco accounts for less than a third of all cancers in males and females.

3. **USFDA to share details of rejected exports with India** – Hindu Business Line

To sign confidentiality agreement with EIC for supplying non-public information. In a move that will enable India take early remedial action on exports rejected by the US, the Export Inspection Council of India is signing a confidentiality agreement with the US Food and Drugs

Administration for prompt sharing of crucial information related to the rejects. Details of all Indian products that are rejected, the reason for rejection, appeals filed, if any, and the final action taken by the US will be supplied to the Export Inspection Council (EIC) by the US Food and Drugs Administration (USFDA) without delay. At present, while India does get to know when a food consignment gets rejected in the US, it does not get to know immediately the details of who the exporter is and what exactly is being objected to by the US. "It is not always due to poor quality that an item faces rejection. Other factors such as not meeting the labelling requirement or the packaging requirement also lead to exports getting rejected. If we know exactly what has gone wrong immediately, and not after a gap of four-five months, we could help the exporter to rectify the situation," the official said.

4. **These were tough pills to swallow** – Hindu Business Line
   This authored article reflects on the list of cases where drug manufacturers faced concerns on certain therapy drugs. **Sanofi** recalled four batches of well known painkiller Combiflam on the grounds that the disintegration time of those tablets was delayed. Thalidomide made by a **German company** was marketed as a sedative mild enough even for pregnant women. Fen-phen was a drug where settlements and damages reportedly amounted to $21 billion. A popular weight loss solution, it was recalled in 1997 after 27 years of being in the market. Diethylstilbestrol (DES) was a hormone prescribed for more than 30 years to prevent miscarriages and other complications during pregnancy. In 1971, it was connected to a tumour that occurred in the daughters of women who had used it. **Merck** had to recall Vioxx (Rofecoxib) after five years of being in the market. It was prescribed as a pain reliever for arthritis but was found responsible for heart attacks and strokes.

5. **New IPR policy aims for 'Creative India: Innovative India' but few kinks remain** – Financial Express
   While the new IPR policy is designed to facilitate the ease of doing business, the seven objectives which the policy lays emphasis on include stimulation of generation of IPRs, strengthening the legal and legislative framework, IPR commercialization and reinforcing the enforcement and adjudicatory mechanisms to combat infringements. The column on IPR policy reflects on the acceptance of it from various sides highlighting that the policy lays emphasis on include stimulation of generation of IPRs, strengthening the legal and legislative framework, IPR commercialisation and reinforcing the enforcement and adjudicatory mechanisms to combat infringements. It has also proposed tax breaks to promote R&D, a loan guarantee scheme to cover risk of failure of IPR creation, and a dedicated cell to promote the creation and commercialisation of IP assets. The policy also makes the department of industrial policy and promotion (DIPP) the nodal agency for regulating IPR in the country. Experts have welcomed the move to make DIPP the nodal agency on IPRs as this single umbrella approach will help leverage linkages between various IP offices. The policy, however, has so far failed to cheer the Indian pharma sector. "Unless the government is ready with funding and programmes to ensure access to medicine for all, any change in the legislative framework will hurt not only the generic industry, but the people of India," DG Shah of Indian Pharmaceuticals Alliance said. Experts also feel that the National IPR policy lacks specifics and won't be enough to foster innovation.

6. **Drawing the red line for drug-resistant bugs** – The Hindu
   India's Red Line campaign to curb over-the-counter use of antibiotics is finding recognition, and could be adopted on a world scale. India's idea of putting a red line on antibiotic packages to curb their over-the-counter sale is now being cited as a model that can be used globally to counter the rising threat of superbugs. In its final report on tackling drug resistant infection released on May 19, the global Review on Antimicrobial Resistance — commissioned by UK Prime Minister David Cameron in 2014 and chaired by economist Jim O'Neill — , says India has led the way so far with its idea of a 'Red Line Campaign' for antibiotics packaging, launched earlier this year and should be considered as a starting point. It recommends that the labelling and symbols used can be improved if needed and then expanded globally. India's Red Line campaign, launched in February this year, began marking prescription-only antibiotics with a

red line to curb their irrational use and create awareness on the dangers of taking antibiotics without being prescribed them. Dr Camilla Rodrigues, consultant microbiologist at Hinduja Hospital, said while there is better awareness among doctors, people too are curious enough to ask. She added that while doctors in most countries don't prescribe antibiotics, in India patients go directly to the chemist or use an old prescription to buy antibiotics. Prime Minister Narendra Modi was quoted as saying that India recognises AMR as one of the major global threats to public health. "We have placed restrictions on the sale of antibiotics by making necessary statutory changes. A campaign has been launched to increase awareness regarding AMR along with national treatment guidelines for antibiotic use." By 2050, unless action is taken, deaths due to AMR could balloon to 10 million each year.

7. **NPPA decision to cut post-surgical drug prices big relief for transplant patients** – DNA
   The NPPA, which controls drug prices, has slashed prices of immunosuppressive drugs like Tacrolimus, Mycophenolate and Ciclsosporine last month. Daara Patel, secretary general of Indian Drug Manufacturers' Association (IDMA), said that the NPPA notification came recently. "As per the notification, manufacturers have to bring down prices. According to my knowledge, this is for the first time the prices of these drugs have been brought down," said Patel. Transplant patients spend lakhs of rupees on surgery and end up spending more on post-surgical drugs, he said. "After surgery, it is compulsory that patients take immunosuppressive drugs lifelong. It is good that NPPA has decided to bring the prices of these drugs to a reasonable level," said Patel.

8. **TB patients protest outside health ministry, promised proper drug regimes from July** – DNA
   Antiretroviral therapy (ART) centres for HIV patients are without the daily FDCs and the five selected states have not yet seen the rollout "due to delays in procurement of the medicines needed for treatment". In a letter addressed to union health minister JP Nadda, TB patients, patients living with HIV who are at the risk of contracting TB, and civil society groups such as the Delhi Network for Positive People (DNP+), asked the minister to keep his commitment of rolling out FDCs for patients on a daily basis. India's Revised National Tuberculosis Control Programme had announced in December 2014 that daily FDCs would be provided in 104 districts across five states.

9. **Clinical trials must to curb rare diseases** – Deccan Herald
   Clinical trials are a symbol of hope for people suffering from rare diseases across the world. Globally, nearly 350 million people live with these ailments and approximately 7,000 rare diseases have been identified so far. There is an urgent need to actively pursue clinical research to meet the needs of over 70 million people living with rare diseases in India. Most rare diseases have no cure and have a high mortality rate, because there is no available treatment for them. Any step to accelerate access to new therapies is most welcome, even a trial drug or therapy may be the right intervention to save the patient's life. Most patients and families with rare diseases are aware of the importance of participating in clinical trials and providing access to personal medical data for research purposes. Time is of critical importance for people with rare diseases. The amended policy in the clinical trials guidelines has given the rare disease community in India a new hope. We anticipate that more clinical research programmes will be undertaken now which will give us faster access to new and urgently needed therapies for the rare diseases.

10. **A brighter future for clinical research in India** – Express Pharma
    Leading upto International Clinical Trials Day, which falls on May 20, **Suneela Thatte**, President, Indian Society for Clinical Research (ISCR), is hopeful that new orders and revised guidelines will herald a renewed wave of progress in India's clinical research scenario. Over the last year and a half, the Ministry of Health and Family Welfare has taken steps to address the challenges posed by regulatory uncertainty and take on board concerns voiced by stakeholder. Regulations were amended and further guidance was given on existing ones. These were significant movements forward and a reiteration of the regulator's commitment to clinical research in the country. The

revised guidelines rationalised compensation and medical management for injuries caused during and because of the participation in clinical research, bringing in a balance between the interests of patients and innovators, and at the same time giving us more clarity in the process. What is also important to note is that for the first time in the world, formulae have been introduced by the regulators for calculating the financial compensation based on the 'no fault' principle. This provides ease of implementation and consistency and helps the sponsor of the trial understand the maximum possible liability and to plan appropriately to protect patient well-being. This has resulted in reduced approval timelines which are averaging six to seven months from submission to final approval as compared to 18 months earlier. One of our greatest challenges is to instill confidence and trust amongst global stakeholders about the evolving and more scientific regulatory environment in India and the fact that there is now a more conducive environment for clinical research in the country.