1. **India needs predictable IPR regime: Novartis** – ET Health

Swiss drug maker Novartis has called for a highly predictable intellectual property rights regime and regulations which reward innovation.

"India wants to develop to the same framework that we have in Europe, Switzerland or US. It is very important that the environment becomes highly predictable and that IPRs are clearly defined," Lutz Hegemann, global head of development established medicines franchise at Novartis Pharma AG said on Tuesday while addressing the Swiss Embassy's public symposium on innovation.

The cost of research and development has increased exponentially over the past 20 years to over $4.6 billion in 2011 and laws need to encourage activities of drug development, said Hegemann. "Beyond intellectual property innovation can be incentivised by strong regulatory mechanism, access to quality medicines and rewarding valuable innovation," he said.

Novartis India Managing Director and Vice Chairman, Ranjit Shahani said: "Looking ahead there is obviously a recognition of fact that India needs to be strong in IPR and I think some of the statements made by the Prime Minister on his recent visits are encouraging."

2. **Lee Pharma to appear for fresh hearing on compulsory licence** – The Hindu Business Line

Hyderabad-based Lee Pharma will have to wait for some more time for a hearing of its plea for a compulsory licence (CL) to manufacture patented diabetes drug saxagliptin.

Although it appeared for a hearing before the office of the Controller-General (CG) of Patents Designs and Trademarks last month, it will now have to appear for a fresh one as a new CG has been recently appointed, an official of the Department of Industrial Policy & Promotion (DIPP) told BusinessLine.

The London-headquartered AstraZeneca holds the patent for saxagliptin.

3. **Centre may cap trade margins on generic drugs in two months** – Mint

The Prime Minister's office (PMO) has asked the department of pharmaceuticals to probe the "astronomical" price mark-ups on generic medicines that drug makers sell through distributors—a move that may be a prelude to a cap being imposed on the margins.

"We are going to come up with a notification capping the trade margins within two months. A panel set up by the government is set to submit a report in this regard," said a senior official in the department of pharmaceuticals on condition of anonymity.

The panel is headed by Sudhansh Pant, joint secretary in the department of pharmaceuticals, and includes representatives of the National Pharmaceutical Pricing Authority, Competition Commission of India and industry bodies.

4. **Cancer vaccines: SC seeks drug controller's records** – The Financial Express

In a PIL related to the quashing of licences of two vaccines used for cervical cancer treatment, the Supreme Court on Tuesday sought records from the Drug Controller General of India, to ascertain if proper procedures were followed during the grant of permission to multinationals to administer vaccines on minor girls for prevention of cervical cancer.

The two drugs in question are Gardasil and Cervarix, manufactured by Merck Sharpe and GlaxoSmithKline, respectively.

A bench headed by justice Dipak Misra asked additional solicitor-general Tushar Mehta to produce the records in this regard and also apprise it about the steps taken by the regulator in pursuance of the 81st report of the Parliamentary Standing Committee on Health and Family Welfare. It also posted the matter for further hearing on Wednesday.

5. **Future of branded drugs in a generic world** – Business Standard

With many of the bestselling patented brands approaching patent expiration, pharma companies are looking at various strategies to 'save' their brands.

According to market research sources, the top 50 pharmaceutical brands come from the top 50 pharmaceutical companies worldwide. Out of the top 10 brands, all are in the declining phase except for Humira and Lanctus. Herceptin is the 9th ranked brand with a low growth of 3 percent. Remicade (infliximab), Enbrel (etanercept), Rituxan (rituximab) and Avastin (bevacizumab) are brands which will lose patent protection by 2019 in both USA and EU. Etanercept has already lost patent protection in February 2015 in the EU and in 2012 in the US. Predicted declines are for all these antibody drugs are expected as the brands already have 'copy-cat' or biosimilar versions already launched or under way in the manufacturing plants of key generic drug players.

6. **IMS Health: Drug spending to jump 30 pct. to $1.3T in 2020** –ET Health

As criticism of soaring prescription drug prices in the U.S. grows, global spending on medicines is expected to rise 3 percent to 6 percent annually for the next five years, according to a new forecast from IMS Health.

The health data firm predicts global spending will increase by about 30 percent cumulatively from about $1 trillion now to about $1.3 trillion in 2020, driven by expensive new drugs, price hikes, aging populations and increased generic drug use in developing countries.

The increase would be higher but for a huge, looming wave of patents for expensive brand-name pills expiring over that stretch, allowing cheaper generic versions to then enter the market.

7. **Dept of pharmaceuticals to meet medical device industry to discuss price caps** – The Times of India

The contentious issue of introducing price caps on exorbitantly priced medical devices is nearing a solution with the department of pharmaceuticals now directing all stakeholders including medical device manufacturers and health ministry officials to thrash it out and arrive at a final decision soon. The department of pharma will be meeting medical device manufacturers, health ministry officials and stakeholders on November 23 to come up with a model to regulate and cap prices, sources say.

Earlier efforts to bring down prices of medical devices have failed as the government has not been able to reach a consensus, with some departments having opposed the move saying it may impede potential foreign investment, as well as weaken the 'Make in India' pitch.The contentious issue of introducing price caps on exorbitantly priced medical devices is nearing a solution with the department of pharmaceuticals now directing all stakeholders including medical device manufacturers and health ministry officials to thrash it out and arrive at a final decision soon. The department of pharma will be meeting medical device manufacturers, health ministry officials and stakeholders on November 23 to come up with a model to regulate and cap prices, sources say.

8. **Taken remedial actions at 2 plants in Maha: Novartis** - PTI

Drug firm Novartis today said it has taken remedial action at its two plants in Western India which had received a warning letter from the US health regulator and expects the manufacturing facility to return to normal functioning soon.

Sandoz, the generic drug arm of Swiss drug major Novartis, had received a warning letter from the US health regulator for violations of current good manufacturing practice (cGMP) norms at its two plants in Maharashtra.

"Two Sandoz plants have received a warning letter from US Food and Drug Administration (USFDA). We have already taken remedial action at these plants and these units would be soon back to normal," Novartis India Managing Director and Vice Chairman, Ranjit Shahani told PTI on the sidelines of an event here.

9. **Local TB kit, if approved, may reduce diagnosis cost** – The Times of India

An indigenous diagnostic kit for tuberculosis is undergoing the final stages of validation and is expected to bring down the cost of diagnosing TB significantly. This was stated by the Director General of the Indian Council for Medical Research (ICMR), Dr Soumya Swaminathan, at a symposium on intellectual property in India organised by the Swiss Embassy.

The new kit is a joint initiative of the Department of Bio-Technology (DBT), ICMR and the health ministry. "The health ministry is looking for diagnostics of high quality that is also affordable," said Dr Swaminathan.An indigenous diagnostic kit for tuberculosis is undergoing the final stages of validation and is expected to bring down the cost of diagnosing TB significantly. This was stated by the Director General of the Indian Council for Medical Research (ICMR), Dr Soumya Swaminathan, at a symposium on intellectual property in India organised by the Swiss Embassy.

The new kit is a joint initiative of the Department of Bio-Technology (DBT), ICMR and the health ministry. "The health ministry is looking for diagnostics of high quality that is also affordable," said Dr Swaminathan. The symposium was dominated by those representing Big Pharma interests who emphasised the high costs of drug discovery based on a study by a research centre heavily funded by the pharma industry with pharma-provided data not open to public.

Speakers included those representing the interests of multinational healthcare companies like Roche, Novartis and Lucentix, and those from law firms that fight the patent cases for these companies in India. They spoke about the need to tighten the patent protection system in India and criticised what they saw as the inefficiencies in the patent granting process.

10. **Don't see disparity in treatment of Indian firms: David Keeling** – Mint
The McKinsey leader speaks on US FDA citing violations by Dr Reddy's Laboratories that brought to the for quality and compliance practices in India's pharma industry.

A warning from the US Food and Drug Administration (FDA) citing violations at three plants owned by Dr Reddy's Laboratories Ltd, the country's second largest drug maker, has once again trained the spotlight on quality and compliance practices in the Indian pharmaceutical industry. The warning is the latest in a string of FDA actions against Indian pharmaceutical firms. Ranbaxy Laboratories Ltd (acquired by Sun Pharmaceutical Industries Ltd), Sun Pharma, Cadila Pharmaceuticals Ltd, Ipca Laboratories Ltd, Wockhardt Ltd and Aurobindo Pharma Ltd have faced action from the US regulator in recent years.

In this context, David Keeling, who leads the global quality, compliance and remediation practice at US-based management consulting firm McKinsey and Co. Inc., says the cost of non-compliance and remediation is 3-5% of sales, in addition to revenue lost on account of product removals from shelves. The remediation time itself is anywhere between five and seven years. "Given what we see today, the choice of being reactive and addressing things after is a bad choice. Organisations need to build quality proactively and from start," he says.

11. **Hilleman to invest ₹300 cr in R&D for low-cost vaccines** – The Hindu Business Line
Merck-Wellcome Trust JV scouting for partners for 'broad' vaccine for meningitis

While the incidence of meningitis or meningococcal disease in India is low, the available vaccine for the disease is 'narrow' and extremely expensive, says Davinder Gill, CEO, Hilleman Laboratories, a 'non-profit joint venture' between US pharma major Merck and UK-based Wellcome Trust.

An IIT- Kharagpur alumnus, Gill has worked with MNCs such as Wyeth and Pfizer, and now steers Hilleman's vaccine R&D lab, in Delhi. He spoke to BusinessLine on his company's about ₹300-crore investments in R&D for affordable vaccines.

12. **The Rs1 trillion FDA impact on Indian pharma** – Mint
The market capitalization of India's top five pharma companies, Sun Pharmaceutical Industries Ltd, Dr Reddy's Laboratories Ltd, Cipla Ltd, Lupin Ltd and Wockhardt Ltd, have fallen by Rs.99,235 crore between the time their stocks touched their peaks in the past year, and Monday.

Much of the fall can be attributed to warnings and import alerts issued by the US Food and Drug Administration (US FDA) on manufacturing plants of the five companies. The US is the world's largest generics (or off-patent drugs) market, and an important source of business for most Indian pharma companies.

13. **Chinese aid norms curb exports of Indian drugs to markets in Africa, Asia & eastern Europe** – The Economic Times
The stipulations increasingly being made by China while extending financial aid to several developing economies to buy medicines produced by their manufacturers have of late begun denting the exports of Indian drugs to these countries. A senior commerce ministry official said India currently exports around $15-billion worth medicines and the stipulations of China are probably affecting India's drug exports in nearly a fifth in some markets in Africa, Asia and eastern Europe.

14. **Health ministry plans to revamp regulatory rules for biosimilar drugs** – The Economic Times
The health ministry plans to revamp guidelines for approving biosimilar drugs to make the regulatory pathway more robust and sync it with the rapidly evolving global landscape. The guidelines were released three years ago.

Biosimilars are copies of complex drugs, which are based on living cells and 'similar' to an original biologic manufactured by the innovator. These drugs stand distinct from the chemical-based generic drugs that are 'identical' to the originator's compound.

15. **Poised for progress** – The Financial Express

From insurance to assurance, the Telangana state government led by Chief Minister K Chandrasekhar Rao is focussing on enhancing the rural healthcare system in the newly-formed state. The one-year old Telangana government is the first state to develop a hospital-specific budget, apparently a first among all the state governments. This essentially focuses on infrastructure augmentation and decentralisation of healthcare delivery. The Telangana government has also decided to increase the plan budget from 40 per cent to 56 per cent from the erstwhile united Andhra Pradesh's allocation of 23 per cent. This move aims to take healthcare to the doorstep of the rural population.

"We believe in decentralisation of healthcare delivery in the state. At present, we have 10 districts, very soon we are planning to create more districts. Once the state forms new districts we will ensure that each district will have state-of-the-art healthcare delivery mechanism in place," says Rao. The budget allocation costs towards hospitals revamp is about Rs 585 crores besides looking at mobile healthcare delivery which facilitates in reaching to the rural and slum population. The state government is looking at convergence of services and education as part of its improvement practices. As part of a hub-and-spoke model, the government is looking at decentralisation of medical services with 'brand Hyderabad' as a focal point.