1. **Will NLEM balance patient interest with sector growth?** – Hindu Business Line

The "best-fit list" is how the latest version of the National List of Essential Medicines (NLEM) is defined by the government committee that worked on it. But will it indeed be the "best fit" in terms of walking the tightrope between patient interest and industry growth?

That's a call that will be made much later this year depending on the implementation of the revised NLEM and its after-effects.

The latest version of the NLEM, unveiled late December, increased the number of essential medicines on the list from the original 348 to 376.

2. **Make way for automatic compulsory licencing in pharma: RSS** – Economic Times

Lauding India's tough stand on the patents issue, RSS affiliate Swadeshi Jagran Manch (SJM) today asked the government not to give in to US pressure and urged it to make provisions for liberal and automatic compulsory licencing of pharma products.

Noting that India is known as the 'Pharmacy of the World' for providing cheap medicines for those affected by blood cancer, HIV-AIDS and other serious diseases, SJM said it should frame policies responsibly.

3. **Roche, Glenmark settle patent litigation over cancer drug** – Economic Times

Swiss pharma major F Hoffmann-La Roche and India's Glenmark Pharmaceuticals have settled out of court a patent litigation over the former's lung cancer drug erlotinib hydrochloride sold under the brand name 'Tarceva'.

Roche, which was granted the patent in India for erlotinib hydrochloride on February 23, 2007, was embroiled in patent disputes with another Indian pharma firm, Cipla over Tarceva.

"Glenmark and Roche/OSI confirm that they have reached an agreement regarding ongoing patent disputes relating to the anti-cancer medicine Erlotinib Hydrochloride," the two companies said in a joint statement.

Also appeared in Times of India, Business Standard, NDTV Profit

4. **Kiran Mazumdar Shaw: Tax breaks for R&D crucial for innovation** – Economic Times
Globally, we're witnessing the dawn of the 'ideas economy' where the pace of a country's technological progress is directly proportional to its investments in research and innovation.

R&D spending has, thus, emerged as a reliable barometer of an economy's innovation capability.

The imperative to be 'future ready' is leading nations to identify key thrust areas for research and innovation, and then nurturing them with the right kind of fiscal incentives, policy support, financing mechanisms, human capital and best-inclass infrastructure.

5. **Drug patent war, FM auction, coal ordinance kept Delhi High Court busy** – Economic Times
The patent war involving domestic and multi-national pharma majors, tussle between the Centre and a private radio channel over FM auctions kept the Delhi High Court busy in 2015 during which it also rapped the Centre for its coal auction ordinance by saying that the legislation "lacked clarity".

Apart from the coal-based industries, another corporate sector which consumed high court time was the pharma sectors with major drug companies battling over who can be permitted to make medicines for diseases like diabetes and cancer which afflict a large percentage of Indians.

However, these pharma matters hardly proved fruitful for Indian generic drug makers like Cipla and Glenmark, who were stopped by the high court from making cheaper variants of respiratory, diabetes or cancer drugs and antibiotics in which patent was held by some other pharma major like US-based Merck Sharp and Dohme (MSD) or Swiss firms Novartis and Roche.

6. **Warning letters for pharma companies galore: Now Cadila Healthcare faces USFDA heat, stock tanks 16%** - FirstPost
It's raining warning letters for home-grown listed pharma companies. After Sun Pharmaceuticals, India's largest pharmaceutical company, was handed a warning letter earlier this month for irregularities at one of its unit, the US drug regulator, the USFDA, stepped up its action and issued a similar warning letter to Cadila Healthcare for quality and non-compliance matters.

The Ahmedabad-headquartered company received a warning letter for its Moraiya formulation facility and Ahmedabad API facility.

7. **Drugs Controller General cracks the whip on online sale of drugs** – Business Standard
The Drugs Controller General of India has directed all state governments to take action against unauthorised sale of medicines on websites.

This comes in the wake of an ongoing public interest suit in the Bombay High Court against their sale online. In October, the court had directed the Maharashtra government to check online sale of drugs.

8. **US health regulator likely to increase inspectors in India** – Hindustan Times
While the US lawmakers are pushing the American health watchdog to increase presence in China and India following the rising cases of counterfeit and substandard drugs, the Food and Drug Administration is likely to add five more inspectors in India.

"Headquarters is planning to add five more inspectors to look after the Indian drug units considering the presence of almost 900 plants exporting drugs to the US," two senior officials engaged at FDA's New Delhi and Mumbai office told HT.

The FDA presently employees only two full-time inspectors for China's 708 plants, and three inspectors for 850 plants in India.

9. **In 2016, better health care?** – The Hindu
   Even as millions of Indians wish each other health, happiness and hope in the new year, they also await news on the new National Health Policy which will become the GPS in our journey towards better health. The draft policy, which was framed by the Union Health Ministry, was placed for public comment just over a year ago but is yet to be adopted as the definitive road map of declared government priorities. This may be because of unreconciled differences in the perspectives of the Health Ministry and NITI Aayog. The impasse has to be resolved over the next few weeks if health programmes are not to be left adrift in uncharted seas.

10. **What pharma will look like in 2016** – Mint
    For the Indian healthcare and pharmaceuticals sector, 2015 was a year of healthy growth driven by mergers and acquisitions, and the bouncing back of domestic market growth. On the other hand, 2016 is seen as a year of hope for further growth boosted by a better US and domestic market, with many policy decisions lined up.

11. **Pharma | Exciting possibilities ahead** – Mint
    The Indian healthcare sector has been growing rapidly, driven by demographic, income and epidemiological transitions over the past decade. In particular, 2015 has been a good year. The pharmaceuticals sector has grown at about 15%, the hospital sector has seen a year of strong margins and new capital investments and medical technology has seen a revival of focus with the new draft medical bill and liberalized rules for foreign direct investment (FDI).

    Overall, the Indian pharmaceuticals sector has seen a healthy year, driven by mergers and acquisitions (M&As) and the bouncing back of domestic market growth. We expect both these trends to continue into 2016 and the next couple of years.

12. **2015 in Review : Rapid strides in Public Health** – ET Health World
    The end of 2015 brings many reasons for celebrations in health sector. We made considerable progress towards achieving the MDGs, SDGs were launched with more ambitious goals so as to move forward on unfinished development agenda. We eradicated polio and eliminated maternal and neonatal tetanus in India. The coming year is likely to see accelerated progress towards polio eradication, roll out of SDGs in countries, Universal Health Coverage, more attention to addressing social determinants of health.

    India seems to be poised to continue to lead major economies and hopefully will have more fiscal space for strengthening infrastructure and social sectors (including health). It is estimated that with 14thFinance Commission recommendations the States will allocate more resources to health and about Rs. 8000 to 9000 Crore more may be available for public health in the country.

13. **Accent on pharmacogenomics** – The Hindu
    The first national conference on 'Clinical Research and Personalized Therapy' in India on the theme 'Clinical trials in the genomic era' was held at Jipmer from December 29 to 31.

    This was organised by Division of Research, and Department of Clinical Pharmacology, Jipmer. C. Adithan, faculty (Research) was the organizing chairman and S. Sandhiya, Asst. Professor of Clinical Pharmacology was the Organizing Secretary.

    The conference emphasized on emerging knowledge in Pharmacogenomics and its opportunities to improve clinical research, personalized therapy and clinical practice. The scientific platform gave a snapshot of current advances in Indian clinical research, especially

application of genomics in clinical trial designs and drug safety, personalized therapy in cancer, diabetes mellitus, cardiovascular diseases and neuropsychiatric illnesses.

14. **National Dept of Biotechnology sees Big Data propelling it to $100 bn industry by 2025** – FirstPost
    The National Biotechnology Development Strategy 2015-20 was unveiled by the Minister for Science & Technology and Earth Sciences, Dr. Harsh Vardhan, and the Minister of State for Science & Technology and Earth Sciences, Y S Chowdary, in the presence of the Secretary, Department of Biotechnology, Dr. Vijay Raghavan and other key stakeholders. The National Biotechnology Development Strategy 2015-20 aims to establish India as a world-class bio-manufacturing hub. It intends to launch a major mission, backed with significant investments, for the creation of new biotech products, create a strong infrastructure for R&D and commercialization, and empower India's human resources scientifically and technologically.

15. **10 health projects didn't take off; Rs 1k cr remain locked** – Deccan Herald
    At least 10 key projects of the Union health ministry didn't take off in the last two years despite having budgetary approval, whereas more than Rs 1,000 crore meant for buying new equipment for new hospitals remains locked since 2013.

    Among those stalled schemes are setting up of an integrated vaccine complex at Chengalpattu, national mental health programme and a healthcare scheme for the elderly.

16. **FDA regulator, widowed by cancer, helps speed drug approval** - Business Standard
    Mary Pazdur's battle with cancer was a factor in Pazdur's willingness to swiftly approve risky new treatments and passion to fight the disease that patient advocates thought he lacked

    Mary Pazdur had exhausted the usual drugs for ovarian cancer, and with her tumors growing and her condition deteriorating, her last hope seemed to be an experimental compound that had yet to be approved by federal regulators.

    So she appealed to the Food and Drug Administration, whose oncology chief for the last 16 years, Richard Pazdur, has been a man denounced by many cancer patient advocates as a slow, obstructionist bureaucrat.

    In her struggle with cancer and ultimately her death in November, Pazdur had a part, her husband and a number of cancer specialists now say, in a profound change at the FDA: a speeding up of the drug approval process. Pazdur's three-year battle with cancer was a factor, they say, in Pazdur's willingness to swiftly approve risky new treatments and passion to fight the disease that patient advocates thought he lacked.