1. **MNC pharma lobby pushes for single drug authority here** – The Economic Times

A lobby group of multinational pharmaceutical companies (MNCs) is pushing for replacing state-based multiple drug authorities with a single body for more effective protection of intellectual property (IP) and patents. The Organisation of Pharmaceutical Producers of India (OPPI), which represents 22 pharma companies, including Abbott, Pfizer, Novartis, Novo Nordisk and Sanofi, also wants specialised patent courts for fast disposal of patents and IP disputes.

Kanchana TK, director general, OPPI, said the government’s move to dismantle Foreign Investment Promotion Board (FIPB) and automatic foreign direct investment (FDI) approvals doesn’t serve the intended purpose unless drug research and development (R&D), innovation and exports are adequately incentivised. “What is worrying global pharma companies in India is the IP protection and unpredictability over ease of doing business,” Kanchana told ET. “The budget did not address our key appeals for a simplified regulatory regime without multiplicity, a stable price control mechanism in consultation with the industry, and a simplified clinical trials regime.” OPPI insists that the government should immediately look at fast-tracking policies that impact human lives. “Decisions on new therapies and new drug approvals should be fast-tracked by circumventing the usual regulatory process while ensuring safety measures in the form of number of clinical trials and data,” she said.

*Also reported by –*

- MNC pharma lobby pushes for single drug authority here – ETHealthworld

2. **Making in India is alright, let’s also ‘Design and Develop’, say pharma industry biggies** – The Times of India

From being a powerhouse of low-cost generics manufacturing, the Indian pharma industry must graduate to building competencies around drug discovery, said experts at the final day of BioAsia 2017 here. "In the pharma sector, we have been 'Making in India'. I would urge the government and others to look at 'Design, Develop and Make in India... China has established itself as the factory of the world, India has the opportunity to establish itself as the design centre,'" G V K Biosciences CEO Manni Kantipudi said, adding that the focus on design and development of drugs will lead to
creation of intellectual property in the country. Aurobindo Pharma president Satakarni Makkapati pointed out that India can emulate the Singapore model, where the country reinvented itself from an investment driven low-cost manufacturing destination to a research driven innovation-led biotech manufacturer. He added that one of the biggest challenges in pursuing R&D in this sector, which is very capital intensive and has a low rate of successful outcomes, is that 'Risk Money' is hardly available in the country. In fact, the trend is that the funding for R&D is shrinking even in developed pharma and biotech hubs such as San Francisco, he added. Apart from the lack of adequate capital, Hospira managing director Srin Srinivasan pointed out that shortage of skills is a major challenge. Ageeing, Kantipudi of GVKBio said: "We are weak in biology and genomics." Responding to industry concerns, department of commerce joint secretary Sudhanshu Pandey said the government has been trying to address the issue related to skills via its NSDC - sector skill council for life sciences, which focuses on building skill sets for this industry. He also added that the government is also working on creating a VC fund to finance such research activities. This apart, he said, the Indian Institute of Chemical Technology, which has several labs across the country, will offer its infrastructure to the industry for setting up incubation centres.

3. **Pharma exports to grow 8-10% in FY17 – The Hindu**
The Indian pharma exports are on course to clocking an 8-10 per cent increase in the current financial year thus almost maintaining the growth registered last fiscal, a senior official of the Union Ministry of Commerce and Industry said on Wednesday. "We should be in the same vicinity," Joint Secretary Sudhanshu Pandey said, while pointing that pharma exports were better than that of many other sectors. A near double digit growth is possible despite the overall contraction and slowdown, he added. The official was speaking to presspersons on the sidelines of the BioAsia 2017 conclave in Hyderabad. According to Pharmaceuticals Export Promotion Council of India, last fiscal the exports were $16.89 billion, an increase of 9.44 per cent over the 2014-15 performance of around $15 billion. Pharmaceuticals contributed to 6.44 per cent of the country’s total exports and generics were the third largest among the principal commodities exported by the country during 2015-16.

4. **India’s clinical trial norms are getting in sync with global standards: Paul Stoffels – Mint**
Paul Stoffels, executive vice-president, chief scientific officer and worldwide chairman, pharmaceuticals, of Johnson & Johnson, talks about restarting clinical trials in India and balancing innovation and pricing of products. Johnson & Johnson (J&J), the world’s largest health care company whose consumer products such as baby powder and shampoos are a household name in India, plans to grow its pharmaceutical business in India through a number of new product launches and is involved in conducting research and development (R&D) activities in the country for novel drugs for the global market. In an interview, Paul Stoffels, executive vice president, chief scientific officer and worldwide chairman, pharmaceuticals, of J&J, talks about restarting clinical trials in India, the importance bringing a new drug to the market and balancing innovation and pricing of products.

5. **Weak pound buoy GSK but drugmaker warns on 2017 generic threat – Daily News and Analysis**
GlaxoSmithKline sales and profits jumped in the fourth quarter, helped by falling sterling, but the drugmaker cautioned profit growth could be impacted in 2017 by generic competition to its top-selling lung drug Advair. Outgoing Chief Executive Andrew Witty, presenting his final set of results, said demand for new medicines was increasing and the company's pipeline of experimental medicines provided fuel for further growth. Quarterly sales rose 21 percent in sterling terms to 7.59 billion pounds ($9.48 billion), generating core earnings per share (EPS) up 45 percent at 26.1 pence, GSK said on Wednesday. Analysts, on average, had forecast sales of 7.45 billion pounds and core EPS, which excludes certain items, of 25p, Thomson Reuters data shows. Core earnings per share, in constant currencies, are set to be flat to slightly lower in 2017, if there are substitutable generic copies of Advair in the United States by mid-year, as many analysts expect. If generics don't arrive, core EPS should increase between 5 and 7 percent.
6. **No links terminated with Gates Foundation: Health Ministry** – Business Standard

The Union Health Ministry on Wednesday said that the reports of India delinking its vaccine programme advisory body from Bill and Melinda Gates Foundation (BMGF) are misleading as the philanthropy outfit continues to collaborate and support the ministry. "Some media reports have suggested that all health related collaborations with the Gates Foundation on National Health Mission (NHM) have been terminated. This is inaccurate and misleading. The BMGF continues to collaborate and support the Ministry of Health and Family Welfare," said a statement from the ministry. National dailies on Wednesday reported that all financial ties of the country's apex immunisation advisory body, the National Technical Advisory Group on Immunisation (NTAGI), with the Gates Foundation were snapped over possible conflict of interest issues arising from the foundation's "ties" with pharmaceutical companies. It was also reported that the NTAGI Secretariat will be now fully funded by the central government. According to the published reports, the NTAGI Secretariat was so far being serviced through the Gates Foundation-funded Immunisation Technical Support Unit (ITSU) at the Public Health Foundation of India (PHFI).

7. **Spend on healthcare to tap demographic dividend: NRN** – The Hindu Business Line

Infosys founder N R Narayana Murthy has called for increase in public investments into healthcare. The country’s dreams to benefit from the demographic dividend could be shattered if it failed to invest in the public healthcare system. Though India fared better in terms of increasing life expectancy and infant mortality rates over the last few decades, it is still way behind than some other countries, he said. Addressing the BioAsia-2017 conference here on Wednesday, he said the contribution of non-communicable diseases in the overall deaths was very high and this was impacting the people in the productive age group of 35 to 65 years. “There is a need to increase the number of physicians by 49 per cent, dentists by 106 per cent and trained nurses by 185 per cent,” he said. Quoting reports, he said the country was not faring well on immunisation ratios as well.

8. **‘Infectious disease mortality rate of India much higher than the US’** – The New Indian Express

The infectious disease mortality rate in India is 416.75 per 100,000 persons which is twice as big than the rate prevailing in the United States of America, according to expert doctors who attended a two-day international symposium on ‘Infectious Diseases and Antimicrobial Stewardship’, held recently at the Amrita Institute of Medical Sciences(AIMS). Doctors of AIMS and University of Michigan (UM) Medical School, US, attended the symposium. “Antimicrobial resistance (AMR) has emerged as a global health challenge due to the lack of new antibiotics and ever-increasing burden of infections caused by multi-drug resistant pathogens. Some important factors responsible for the rising antibiotic resistance in India are indiscriminate use of antibiotics, over-the-counter availability of antibiotics, lack of regulatory bodies approving antibiotics and public awareness about antibiotic resistance, injudicious use in veterinary practice, overburdened health infrastructure, and inequity in healthcare,” said AIMS medical director Dr Prem Nair.

9. **An Inadequate and Misdirected Health Budget** – The Wire

The draft National Health Policy (NHP) 2015, based on the core principles of equity, universality and affordability, had set three major objectives for the public health sector: expanding preventive, promotive, curative, palliative and rehabilitative services to improve population health status; assuring universal availability of free, comprehensive primary healthcare services; and significantly reducing out-of-pocket expenditure by ensuring affordable secondary and tertiary care services. These booming ambitions, though, were promptly toned down, “taking into account the financial capacity of the country” as it set minimalist fiscal targets for itself: public health expenditure of 2.5% of GDP, 40% of which – i.e. 1% of GDP – would come from the central expenditures.
Out of 2,36,329 clinical studies being done globally, only 3,016 studies are being done in India. It is much behind countries like the US, Europe, Japan, China, Malaysia and Taiwan and ranks 5th in Asia. South Asia contributes 3,642 studies, Afghanistan contributes 18, Bangladesh 248 with 2 in Bhutan, 71 in Nepal, 348 in Pakistan and 51 in Sri Lanka. Even as more rational guidelines in 2015 were poised to strengthen clinical research in India, out of the 107 clinical studies reviewed and approved to be conducted in the country, 43 were global clinical trials till the period ending August 2015. This is much below as compared to the year 2014 where 150 clinical studies were reviewed and approved out of which 87 were global clinical trials. This is however contrary to the fact that the government is considering to rationalise and has revised certain guidelines related to providing ancillary care to the clinical trial participant to giving no fault compensation for any serious adverse event during the clinical trial. Among other such issues which have been streamlined were related to capping the number of studies an investigator can undertake and also number of beds a hospital need to have for conducting the trial.