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1. **Don't tamper with patent laws** – Hindu Business Line

The Centre is needlessly apologetic about our IPR laws. It set up an IPR 'think tank' in October 2014, perhaps responding to a view that our IPRs are not strong enough to invite foreign investment. Last January, Prime Minister Modi and President Obama issued a joint statement which "committed to establish an annual high-level Intellectual Property Working Group". In November, Modi said in Singapore that "India is committed to protect the intellectual property rights of all innovators". And now, the Cabinet is expected to discuss a 'new IPR policy' in a month.

It appears that MNCs have lobbied with world governments after two setbacks in 2013.

Why dismantle this system? Our IPRs laws should be non-negotiable.

2. **2016: Drug-makers seek a prescription to stay alive** – Hindu Business Line

A major event on the global pharmaceutical landscape that will unfold this year is Pfizer's $160-billion deal to buy Botox-maker Allergan. The "tax inversion" deal raised eyebrows as it sought to reduce US drugmaker Pfizer's tax by shifting its legal base to Ireland.

But the transaction also brought home another message — that the big-ticket merger and acquisition (M&A) route to growth is both alive and well.

More such deals are expected this year, as companies pull out all stops to stay in the race. A race to survive, that is fraught with risks from drug development to marketing. Companies face the constant challenge of whether their investments in research bring in the breakthrough drugs. And if they do, then comes the pricing predicament — of keeping it viable for the company and affordable to the paying patient.

3. **Clinical trials and vaccine cases** – Hindu Business Line
Clinical trials are a contentious issue in the country, and an ongoing case at the Supreme Court is expected to come up on January 12. The Court had been approached to bring in stringent rules and greater transparency into the manner in which trials are done in the country. And over the last three years, under the apex court's watch, the government has streamlined the regulatory process, keeping the patient at the heart of these changes. Another case involving the shutting down of public sector vaccine makers is also expected to come up at the Supreme Court on the same day. A Public Interest Litigation had raised the issue, questioning the then Government's decision to shut down these units over six years ago.

4. **Need to have a national health policy: DMK treasurer MK Stalin** – Economic Times
Advocating the need to have a Natonal Health Policy to provide quality healthcare to all sections of the society, DMK treasurer M K Stalin on Sunday assured that health and education will be the top priority of DMK, if came to power in the 2016 assembly election.

With new diseases emerging, affecting all sections of the society, particularly rural masses, there was urgent need to evolve a national health policy, considering both communicable and non-communicable diseases, Stalin said ..

5. **MNCs play proxy war against Indian generics** – Deccan Herald
Recently, a spate of accusations against Indian drug manufacturing companies by Food and Drug Administration (FDA; the drug regulatory authorities of the US) have been noted. During last year December, Sun Pharma's two plants and Dr Reddy's three plants had received warning letters from the FDA drug authorities for quality issues. In addition, Ranbaxy, now part of Sun Pharma, and Wockhardt are under the FDA scanner for the past few years.

The violations of Indian generic drug companies, noted by FDA, are not so serious and are mostly related to lack of proper data maintenance or issues with manufacturing processes at the plant level. Usually the FDA gives warning letters and suggests guidelines for corrections as well within a stipulated period of time. Most Indian generic drug companies are exuding confidence that they will overcome the hurdles set by FDA. But what is glaring is the media attention that it has been receiving, and this has created a false image about the Indian generic industry.

6. **LIFT RESTRICTIONS ON CLINICAL TRIALS: ISCR** – Hindustan Times
Indian Society Clinical Research (ISCR) members said that more revisions are required in the regulatory norms set by the Drug Controller General of India (DCGI) during its 9th annual conference on Saturday.

The body wants the government to lift the cap on the number of clinical trials and streamline and fast track approvals for clinical trials. "The present regulatory norm allows any doctor to undertake only three clinical trials at any given time," said Suneela Thatte, president, ISCR, adding, "This means that scores of patients are missing out of entering these clinical trials because of the restriction."

7. **'Pharmaceutical lobby in India is weak'** – Deccan Herald
S K Vyas is an independent pharmaceutical professional with over 45 years of experience in the industry. In an interview with Deccan Herald's Sunil Raghu, he says Indians generally like to work and not maintain records.

Indians have been getting huge value by selling generics and so everybody wants to get in to the US market. Initially, people set up a new dedicated plant in consonance with all the guidelines. When the US regulator comes in to check the facilities, the manufacturers get clearances and they begin to manufacture and supply to the US market. Once they get the approval, they begin to get into multiple generics. Over time, their plants become older and when inspection comes, the trouble begins.

8. **StatsGuru: Tracking what hinders research in India** – Business Standard
   At the Indian Science Congress, Prime Minister Narendra Modi called for a revival of research in India.

9. **AMRIT store at AIIMS gives relief from expensive drugs** – Hindustan Times
   Medicines for cancer and heart diseases are being sold at prices that are 56% to 90% lesser than the MRP at India's first AMRIT (Affordable Medicines and Reliable Implants for Treatment) store at AIIMS.

   The store, opened by HLL Llfecare Ltd (HLL) in collaboration with the Union health ministry on November 15 last year, procures and sells such medicines at minimal profit to everyone who produces a prescription, irrespective of their economic status.

10. **Access to medicines: India's strides since independence** – Express Pharma
    Leena Menghaney, Regional Head, MSF Access Campaign, South Asia, in this article, explores milestones in policies that have had an impact on the production, supply and availability of affordable medicines from 1947 to the present day.

    India's journey in healthcare began with immense challenges – high rates of mortality due to malaria, TB, small pox, leprosy, malnutrition and infections, added to which were the highest drug prices in the world for the first generation of antibiotics and essential medicines.

11. **'Healthcare and pharma sectors should work in sync with each other'** – Express Pharma
    Dr Suresh Saravdekar, Medical Consultant (procurement for Pharmaceutical and Medical devices) Municipal Corporation of Greater Mumbai, in a tête-à-tête with Raelene Kambli, points out that India needs a single healthcare policy to resolve its concerns revolving around affordability, accessibility and quality

12. **Indian pharma sees relevance of 'Make in India' programme if government enables regulations and infrastructure** – Pharmabiz
    Indian pharma industry sees that support from the government in the form of enabling regulations and infrastructure are imperative for the success of the 'Make in India' programme.

    "We have emerged as a role model globally in being self-sufficient in generic formulation. In order to sustain this current competitive advantage and to help extend our capability in new areas, the government will need to play a critical role in helping the lifesciences industry to achieve its full potential", said Pankaj Patel, chairman and managing director, Zydus Cadila and senior vice president, FICCI Pharmaceutical Committee.

    The 'Make in India' is more relevant now with the efforts of the industry to look at import substitution. Now this programme is seen to be a great way to cover the healthcare needs. While we are in the right direction, a key concern is that this programme is now seen to create large scope for employment opportunities," pointed out Annaswamy Vaidheesh, vice president, South Asia and managing director, GlaxoSmithKline.

13. **Industry wants centre to move beyond discussions to make India a global manufacturing hub** – Pharmabiz
    The medical devices industry in the country heaved a sigh of relief over the first-of-its-kind initiative taken by Department of Pharmaceuticals (DoP) to reach out to the industry with collaborative intentions to establish medical devices industry in India and make it a

manufacturing hub of the world. However, experts warned that mere exhibitions will not ensure the desired objectives of making India a powerhouse of medical devices, as the sector needs to move beyond discussions to policy interventions.

14. **Sparks fly at Express Pharma debate on online pharmacies** – Express Pharma
Express Pharma, a leading publication from The Indian Express Group, flagged off the first edition of Vantage Point, a platform to discuss and deliberate on India's most pressing and controversial topics. The debate on 'Online Pharmacies: Game Changers or Trouble Makers' was held on January 8, at the Express Towers, Nariman Point, Mumbai.

    Though there was a consensus on the dire need for change in regulatory mechanisms, with inputs from all stakeholders, panelists remained divided on basic issues. This topic will no doubt be up for debate once the regulators make their move.

15. **Zydus Cadila launches copy of Roche's breast cancer drug Herceptin** – Economic Times
Zydus Cadila has introduced a breast cancer drug in India that is a copy of Swiss giant Roche's product Herceptin, which had global sales of about $6.6 billion in 2014 and has been involved in legal tangles.

    Roche, which sells the product in India as Herclon, has taken legal action against two Indian companies for making copies of the drug, contesting their claims of similar efficacy.

    Last year, Roche had taken Reliance Life Sciences to the Delhi High Court, seeking to block the launch of its product, objecting to claims that its benefits are similar to trastuzumab. The official spokesperson at Roche India did not comment on whether the company is contemplating legal action against Zydus Cadila as well.

16. **Drug maker Wockhardt on fast track of innovation** – Economic Times
Indian drug maker Wockhardt has quietly been conducting discovery research in a narrow range of potent anti-infective compounds, which, if successfully developed, promise to fight life-threatening pathogens and vindicate the company's perseverance in staying on course through the past two decades.

    Wockhardt's experimental antibiotic drugs a priority review status called Qualified Infectious Disease Product (QIDP), which accelerates the drug development cycle in addition to providing a five-year extension of the exclusivity period, post approval.

    This has fuelled Wockhardt's ambitions to go full throttle into further developing the drugs, vaulting it into the pack of A-listers of select global drug makers including Roche, Merck, Pfizer and AstraZeneca that have stepped up interest in the same area lately.