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IPR and Innovation

1. [Indian co seeks compulsory nod for MNC's drug](#) – The Times of India

A little-known Hyderabad-based pharma company has filed an application with the Patent Office to manufacture saxagliptin, a diabetes drug patented and marketed in the country by MNC AstraZeneca. This is the third compulsory licence application filed so far, in a bid to substantially bring down the cost of a key drug used in diabetes management.

Lee Pharma filed the application on June 29 to make a generic version of the patented drug, marketed as Onglyza, under Section 84 of the Patent's Act, 1970. The first compulsory licence Natco's application for Bayer's Nexavar, an anticancer drug was successful, while the second BDR's application for BMS' Dasatinib was rejected by the Patent Office. The domestic company, in the latest application, says that the drug is being sold by Astra Zeneca at Rs 41-45 per tablet, while the cost of importing is less than a rupee (0.80) per tablet.

2. [A patented innovation from Zota Healthcare](#) – Pharmabiz

Zota Healthcare has given a new direction in treatment of common cold therapy and recently received a patent for their innovation.

Dr. Sanjay Agrawal, medical consultant and official spokesperson, and a man behind this innovation has confirmed about this recent development. According to him the new drug which will be commercialized shortly in India and abroad will add a new perspective in the treatment of common cold and will provide unmatched benefits to patients in terms of efficacy and safety. This will prove to be a path breaking therapy and will receive great acceptance from the medical field as well like for all his earlier innovations, he added.

3. [NIPER sold patent to commercial Pharma company for less than Rs 20 lakh](#) - The Daily Mail

July 5, 2015: After failing to commercialise its research patents, National Institute of Pharmaceutical Education and Research (NIPER) recently sold a patent to a Gurgaon-based Pharma company, Windlas Biotech Limited for peanuts. While NIPER authorities did not reveal details of the deal even after a month, Mail Today spoke to a chief functionary at Windlas Biotech, Hitesh Windlas who said the patent was acquired by paying less than Rs 20 lakh. "I cannot reveal the details but the patent cost is below Rs 20 lakh. It requires improvement and we have employed our own scientists.

"We are planning to get the patent registered in European countries after it becomes commercially viable," Hitesh said. Former scientists have alleged that the institute lacks transparency, a secret competitive bidding system and overlooked national interests for personal gains which caused a huge loss to the nation in terms of revenue and development in pharma sector.

Access to Healthcare

1. [Modern Family Doctor plans 300 clinics across India](#) – Business Standard

July 4, 2015: Modern Family Doctor, a Bengaluru startup that aims to bring back the concept of neighbourhood family doctors or general physicians, will increase its presence in smaller towns to provide primary care to patients. The firm plans 300 clinics across India in three years, expanding from its current 51 in the two cities, Bengaluru and Pune. [Modern Family Doctor](#) plans to set up a round-the-clock call centre, too.

Modern Family Doctor aims to fill a gap that exists in the private sector, that of providing primary healthcare in smaller towns. "The lack of good primary healthcare is very apparent in India because hospital outpatient departments are flooded with patients; 70 per cent of whose needs are primary in nature but they have no other option. Going to a hospital means travel, time, inconvenience, exposure to infections, and higher expense," said Naresh Malhotra, Chief Executive Officer, Modern Family Doctor.

2. [SBTC to soon set up 10 metro blood banks across Maharashtra](#) – Pharmabiz.com
July 6, 2015: State Blood Transfusion Council (SBTC) is in the final stages of setting up 10 metro blood banks in 10 districts across Maharashtra to address the primary healthcare needs of the urban poor as part of the National Urban Health Mission (NUHM). At the present, there are 250 blood banks in the state, which are licensed and registered.

Collection of blood, its testing and its distribution is done through these blood banks. The plan to set up metro blood banks according to officials will strengthen the existing 41 district-level blood banks across the state.

Medical & Regulatory

3. [NPPA seeks details of price movement of certain ortho implants](#) – The Economic Times
July 5, 2015, NEW DELHI: The national drug price regulator, NPPA, has sought details from some medical device companies regarding the price movement of certain orthopaedic implants in last three years. While rejecting the contention of these firms that medical devices are not covered by the provisions of Drug Prices Control Order (DPCO), 2013, National Pharmaceutical Pricing Authority (NPPA) has given them a week to respond.

"This is with reference to clarification sought by some companies regarding applicability of the provisions of DPCO, 2013 in case of medical devices," [NPPA](#) said. In its earlier letter dated May 15, 2015, it had clarified that Para 20 of DPCO, 2013 provides for monitoring of the non-scheduled formulations. "Orthopaedic implants along with other medical devices are notified as 'Drug' under the [Drugs](#) and Cosmetics act 1940 and rules thereunder. Therefore, your contention that the provisions of DPCO, 2013 are not applicable to medical devices is totally incorrect," the letter said.

4. [Parliamentary panel asks govt to provide insurance cover to all HIV positive patients](#) – Pharmabiz.com
July 6, 2015: The Department-Related Parliamentary Standing Committee on Health and Family Welfare has recommended to the government to provide both life and health insurance cover to all HIV positive people without any discrimination preferably at normal rate of premium. The Committee headed by Satish Chandra Misra, had recently submitted its report to both Houses of Parliament. In its 85th report, the Committee had given its green signal for the controversial Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Bill, 2014 and has recommended to the government to pass the Bill without further delay.

5. [DoP to launch Technology Upgradation Scheme for SMEs for quality improvement](#) – Pharmabiz.com
July 6, 2015: The Department of Pharmaceuticals (DoP) is formulating a scheme for technology upgradation of the pharmaceutical companies in the small scale sector as part of the government initiative for quality improvement in drugs production, according to Dr V K Subburaju, secretary of DoP. The government will provide financial assistance under this scheme to the manufacturing firms through financial institutions. The department will introduce the project with an initial outlay of Rs.500 crore, he said while inaugurating the second edition of 'Pharmac South', in Chennai, a trade exhibition by pharma companies in the southern states.

6. [New financing model to be compatible with pharma sector's special needs](#) – Financial Express
July 6, 2015: With export-oriented Indian pharma companies facing stiff competition from China and a close scrutiny of foreign regulatory agencies, the commerce ministry and the Exim Bank of India will soon unveil a financing model compatible with the sector's special needs: Longer-term loan with an extended moratorium period. Currently, commercial banks extend loans to the sector with only a five-year-tenure and one-year moratorium period, as it does in the case of most other industries.

Exim Bank, sources said, has begun extending term finance to pharma companies with a maximum repayment period of 10 years and with a moratorium of up to 36 months (meaning, principal repayment can be deferred by three years and only the interest needs to be paid during the moratorium period). The longer-term loan is to help export-focused pharma firms set up high-quality facilities (including for R&D) that meet global standards, so as to obtain approvals from regulators including the US Food and Drug Administration (FDA). The loans can also be used to help Indian pharma companies (including through joint ventures overseas) acquire companies, tangible assets and brands abroad.

7. [Haryana asks Centre to amend Drug Act](#) – The Statesman

July 5, 2015: Haryana government on Saturday urged the Union government to amend the Drugs and Cosmetics Act to ban nicotine which is now readily available in the market. Haryana Health Minister Anil Vij said he has sent a proposal to Union Health Minister J P Nadda to ban nicotine gum and for amending the relevant Act so that it is not easily available and people are saved from its harmful effects.

He also said that the provision of relaxation of certain limit of nicotine under the schedule of sales license should be withdrawn. Vij said the state government has already included nicotine in the category of toxics under Haryana Toxic Ownership and Sales Rules, 1966. Nicotine could be extracted from anything. To get or sell nicotine, any person or a shopkeeper could take support of prevailing Act which is harmful for the society. Therefore, the Central government has been urged to make appropriate amendments in the Act, he said.

8. [Pharma industry sets higher targets](#) – The Hindu

July 6, 2015: A two-day national exhibition of pharmaceutical and nutraceutical industries in south India, 'Pharmac South-2015' was held at Chennai Trade Centre recently with participants deciding to augment their contribution in the next fiscal. The theme was 'Destination for innovative and reliable formulations and healthcare products'. While inaugurating the expo, secretary, department of pharmaceuticals, Ministry of Chemicals and Fertilisers, V.K. Subburaj, said "It is a good sign that the export of drugs from the country has crossed Rs. one lakh crore. However, more efforts are needed from them to raise it over the next 10 years."

While urging the pharma industry to spend more on research and development of molecules, Mr. Subburaj said that all departments concerned are working in tandem to reduce India's dependence on imports in the medical devices sector. The secretary said there was a need to boost the sector's manpower to improve drug quality in India. P.V. Appaji, director-general, Pharmexcil, said that in 2014-15, 55 per cent of Indian Pharma's exports went to developed nations, which shows the strength of the growth. IDMA president S.V. Veeramani said the market situation had improved.

9. [Rajasthan fares poorly on child healthcare: Unicef survey](#) – The Times of India

July 6, 2015: JAIPUR: The results of Rapid Survey on Children (RSOC) 2013-14 have once again caught Rajasthan napping on children's health count. The report, which was only partially released due to poor outcome particularly in BJP ruled states, is prepared jointly by the Unicef and Union government. Rajasthan has recorded the highest number of girls in the country (65.2%) between age 15 and 18, who have body mass index (BMI) less than 18.5 (low weight). Out of total cases, 68.6% of low BMI was reported in rural parts of the state.

In the social category, girls from scheduled class (SC) are worst off where a total of 70.2% in the particular age group were reported to have low BMI. Another area where Rajasthan has the worst performance is the early marriage of girls. The national average is 21.1 years.

10. [States should create a separate ministry of AYUSH: Shripad Yesso Naik](#) – Financial Express

Recently Union Ministry of AYUSH advised the state governments to create a separate ministry of AYUSH with the view that with the ministry in place, the states will at least have a directorate to work in the area of AYUSH promotion which will create employment opportunities for local AYUSH doctors. In an exclusive interview with EC's Mohd Ujaley, Union Minister of State for Health & Family Welfare, Shripad Yesso Naik, says "In future, we are also aiming to have one AYUSH doctor in every primary healthcare centre across the country."

There is lot of criticism of your government for not adequately focusing on healthcare and also slashing the budget for health. What have been the major achievements of your government in healthcare in last one year?

I think, the facts related to healthcare are misplaced. We have not slashed any budget. With new tax devolution formula, share of state governments in central taxes has increased from 32% to 42%. Therefore, in some of the schemes now states are bound to take the lead. For us health is one of the key focus area. Our National Healthcare Policy 2015, clearly put the focus back to the quality, affordability and availability

of healthcare in the country. If you look at what has happened earlier, due to poor policy, the cost of healthcare increased tremendously, benefiting the private companies, not the common-man.

11. [2 bodies oppose cap on medical device prices](#) – The Economic Times

July 3, 2015: NEW DELHI: Even as the government is trying to tighten the regulatory noose around medical devices such as stents, catheters and implants to bring down their prices, some of its departments have opposed the move saying it may impede potential foreign investment in the sector as well as weaken the 'Make in India' pitch, official sources said. In a recent review meeting at the Prime Minister's Office (PMO), two key departments of the government- department of industrial policy and promotion (DIPP), and department of pharmaceuticals (DoP) - dealing with medical devices - have raised concerns on the government's initial proposal of having a separate pricing policy for medical devices, in line with that of medicines.

"DIPP and DoP are of the view that price caps on medical devices at this point in time are likely to hamper the growth of the sector which is too new and have limited players. Moreover, price regulation has the potential to dissuade foreign investors who have committed investments in the sector," the official, privy to developments, told TOI. Currently, almost 75% of high-end medical devices used in the country are imported, while there are merely 10-11 domestic firms making some kinds of stents and implants in India.

12. [With provision for jail term, clinical trial norms to get a shot in the arm](#) – The Times of India

July 5, 2015: NEW DELHI: [The government is planning to add more teeth to clinical trial rules so that violators attract stringent punishment, including imprisonment](#), besides hefty fines in even cases where the patient is not directly impacted during the experiments with new medicines. The changes are part of the Drugs and Cosmetics Amendment Bill, 2015 which is likely to be tabled in Parliament during the upcoming monsoon session, official sources said.

Following the rising number of deaths during clinical trials leading to strict directives from the Supreme Court, the health ministry framed specific guidelines and protocol for companies conducting clinical trials to test new products. Accordingly, the government plans to introduce stringent laws for those violating these protocols, the sources said. The proposed changes include a provision for a year of imprisonment if violation of rules leads to any kind of adverse impact on the patient enrolled in clinical trial. The new law would also make it mandatory for the companies conducting trial to pay fine of up to Rs 3 lakh in case of any error or violation of the protocol even if the patient is not directly impacted, the sources said.

13. [Rs 30 crore cleared for buying GMCH medicines](#) – The Times of India

July 5, 2015: NAGPUR: Union minister for surface transport [Nitin Gadkari](#) and Maharashtra medical education minister Vinod Tawde here on Saturday showered a bunch of promises on the two government medical colleges in the city in an effort to resolve many long pending issues faced by them. The ministers were at Government Medical College and Hospital (GMCH) for the first meeting of the 'board of visitors' of GMCH after the formation of the new government and the new body. Gadkari being the chairman of the board listened to various issues and offered support from the Centre in availing all the union government's schemes, especially for raising funds for completion of infrastructural requirements at [Indira Gandhi Government Medical College \(IGGMC\)](#).

The biggest gift came GMCH way, with Gadkari bringing along with him Tawde, was the provision for an outlay of Rs30 crore for purchase of medicines for GMCH. Dr A Niswade said that now the dean will also have the power to spend this money without seeking permission from higher authorities. Till now, this outlay for GMCH was just Rs9.6 crore.

14. [Medical Shops to Display Site Info to Report Overcharging](#) – Indian Express

July 4, 2014: CHENNAI: Soon, every single medical shop across the country will have to prominently sport a sticker urging it's patrons to send an e-complaint if they're being overcharged. This was to popularise the recent initiative — Pharma Jan Samadhan (PJS) — online consumer redressal forum accessed via smartphone, Dr V K Subburaj, Secretary, Department of Pharmaceuticals, Government of India, said on Friday.

“The PJS was launched to handle the growing number of complaints that pharmacies are overcharging or not selling certain medicines that are affordable. But, it has not reached the public the way we imagined. To ensure that everybody knows about it, we will get all pharmacies to sport stickers with the website address prominently,” he explained.

15. [40 AMCs identified for access to WHO database for effective drug monitoring](#) – Pharmabiz.com

July 4, 2015: Out of the 150 ADR Monitoring Centres (AMCs), 40 AMCs have been identified for registration with the Vigiflow software which is meant to report adverse drug reaction (ADR) data to World Health Organisation (WHO) database on a consistent basis, as a part of the Pharmacovigilance Programme of India (PvPI), informed an official associated with the development. Currently 110 centres have the Swedish software Vigiflow which helps in accurate reporting of ADRs with the help of Technical Data Associates (TDAs) working in the ADR monitoring centres as of today. They are working in coordination with Indian Pharmacopoeia Commission (IPC) Ghaziabad for final analysis and reports.

TDAs are accountable to collect information from the patients, perform follow up with them, enter information in the prescribed software (Vigiflow) and sending them to IPC for further analysis and documentation. IPC has been assigned to update information on ADRs that is being reported in India from across all its centres through VigiFlow to the Uppsala Monitoring Centre (UMC) in Sweden, which is WHO's collaborating centre for international drug monitoring.

16. [TSDCA launches new website for online issue of licenses to pharma cos](#) – Pharmabiz.com

July 4, 2015: The newly formed Telangana drug control administration (TSDCA) has launched its new website offering online services to pharmacists and pharmaceutical manufacturing companies in the state. With this launch of online services, now pharmacists and pharmaceutical manufacturers can obtain licenses and manufacturing approvals by submitting their information online and can get permission from TSDCA on a time bound manner. This will also resolve problems faced by pharmacists and manufacturers like unreasonable delays, lack of transparency and corrupt practices by the authorities.

While launching the website, Dr Laxma Reddy, minister for medical, health and family welfare, said that pharmaceutical industry and pharmacists in the erstwhile Andhra Pradesh suffered a lot. Now the Telangana government wants to create a conducive and encouraging environment for the industrial sector and build up the confidence among the investors, through transparent and accountable governance. For this, the state government is keenly looking at utilizing the information technology services in every sphere of its governance.

4. [AIOCD asks DCGI to stop indiscriminate internet drug trade for patients safety](#) - Pharmabiz

July 4, 2015: The All India Organisation of Chemists & Druggists (AIOCD), a representative body of nearly 5.5 lakh members engaged in pharmaceuticals retail and wholesale trade, has demanded to the Drug Controller General of India (DCGI) to take immediate measures to notify to stop the indiscriminate internet drug trade and save the public from its probable harmful effects. “E-pharmacies in whatever form or model now operational in India are unlawful and current set of law does not allow to operate e-pharmacy,” said JS Shinde, president, AIOCD.

Though pharmacy profession is evolving in India, our members have served public even to rural population and remote areas of this country over decades. Medicines cannot be compared with any other common commodity. Three important basic factors—doctors, pharmacists and consumers-- are essential elements in medicine dispensing. Hence, it is not like a grocery items or cloth, which can be bought directly online without consulting anyone, Shinde said.

5. ['E-pharmacies prone to misuse'](#) – The Times of India

July 5, 2015: HYDERABAD: While the entry of online pharmacies in the market might be making it easier for patients to buy medicines without having to make the commute to the store, the e-pharmacy model has come in for criticism from the Drugs Control Administration as well as Telangana Pharmacists' Association. Reason: The two laws governing sale of drugs — Drugs and Cosmetics Rules (DCR), 1945, and Drugs and Cosmetics Act (DCA), 1940 — are silent on e-pharmacy outlets, thereby making the model not only illegal but also prone to misuse, especially when sedatives and pain-killers are being sold online without prescription.

As it turns out, the All India Organisation of Chemists & Druggists (AIOCD), which is the national representative body of around 5.5 lakh pharmaceutical retail and wholesale traders, has asked the Drug Controller General of India (DGCI) to ban the sale of drugs through e-pharmacy. "Medicines cannot be compared to any other commodity. It is not grocery or cloth, which can be bought online without consulting anyone," said AIOCD president JS Shinde in a statement ahead of a meeting of the state directors of the drugs control administration.

Others

1. [Is India doing enough for public health? – Hindustan Times](#)

India's the pharmacy of the world, manufacturing 60% of the world's life-saving vaccines and close to half of its generic drugs. Its skilled medical professionals and technically-advanced hospitals have made it one among the world's top five medical tourists destinations, where close to 2 lakh overseas patients arrive each year seeking high-quality, low-cost treatment and care.

Yet, it faces mindboggling shortfalls in healthcare delivery to its own populations, forcing millions to seek treatment in the private sector. As much as 70% of India's health spending is out-of-pocket, with the private clinics and hospitals providing 80% outpatient and 60% inpatient treatment. With regulation varying widely across states, this treatment is often inadequate and inappropriate, and almost always unaffordable.

2. [State's newborn screening programme wins laurels – The Hindu](#)

The Health Department's newborn screening programme in which all babies born in government hospitals undergo mandatory screening for four congenital metabolic disorders, which can have long-term and irreversible developmental outcomes, has emerged as one of the most innovative and well-managed programmes to have been taken up by the department. The programme was selected the top innovation in the area of child health in the country at the on-going National Summit on Good and Replicable Practices and Innovations in Public Healthcare System in India, being organised by the Union Ministry of Health & Family Welfare. The programme was launched by the State in September 2012.

Under the programme, babies are screened for four metabolic disorders — congenital hypothyroidism, phenylketonuria, congenital adrenal hyperplasia, and Glucose 6 phosphate dehydrogenase deficiency. "Of the 1.4 lakh newborns we screened so far, 70 babies were found to be having congenital hypothyroidism, two had congenital adrenal hyperplasia, while nine had G6PD deficiency. All of them are currently being treated and regularly monitored by district-level committees.

3. [Dengue watch: ban on OTC sale of anti-inflammatory medicines – The Hindu](#)

July 5, 2015: [From August 15 till November 30; to be sold by chemists only on the basis of prescription](#)

School children will be 'enrolled' this season as the new ambassadors to keep dengue and malaria at bay, as per orders issued by the State health minister Satyendra Jain, who has recently reviewed the preparedness for dengue and other vector borne diseases. Also all NSAIDs drugs (Aspirin, Dispirin, Brufen, Voveran, etc.) will be banned from August 15 till November 30 for over the counter (OTC) sale by chemists. It will be sold by chemists only on the basis of prescription by qualified doctors. "All advisories regarding dengue and its management with respect to government and private hospitals, dispensaries, laboratories, and general public is to be re-drafted and simplified. The misconception, particularly regarding platelets count amongst general public and healthcare providers, will be clarified in the said advisories," said Mr. Jain.

Meanwhile, school children will be roped in to demonstrate the life cycle of Aedes mosquito. "They will be involved in dengue control activities, given projects at school related to dengue and cards will be given with checklists for them to check breeding of mosquitoes in their own households and 10 other neighbourhood households, to be duly signed by their parents also," noted a release issued by the Department.

4. [Editorial: Curing healthcare – Financial Express](#)

July 5, 2015: Though private healthcare costs a lot more than public healthcare—the latest NSS health survey says hospitalisation differences are 4 times—over 70% of rural and urban Indians get themselves treated at private sector facilities. While there are certainly instances of private care being better than that of the public sector, the reason for the preference for private treatment is simple: the public sector simply doesn't have the funds to develop the kind of healthcare that India needs. Indeed, as compared to some of

India's BRICS peers that spend much more—Brazil and China spent 4.7% and 3.1% of their GDP in 2013—India just spent 1.3%.

What the public sector has, though, is abundance of infrastructure—getting land and all the required permissions is a major pain-point for the private sector. In which case, the obvious solution is a marriage of the public sector's infrastructure with the private sector's ability to spend and organise better. More so since, according to estimates, India's healthcare needs are likely to double in just the next 5 years. In the past, several such instances of public private partnership have failed miserably with the private sector failing to deliver on promises, say, that a fourth of all hospital beds will be reserved for the poor.

5. [Summit address issues of treatment barriers in heart diseases](#) – The Times of India

July 5, 2015: PUNE: Experts gathered at the cardiovascular summit held in Pune on Saturday (July 4) discussed the prevalence of the disease conditions in India, diagnostic options and therapies available along with the overall state of healthcare innovation while addressing the barriers to increasing the access for the treatment to patients. The two-day-long summit brought together noted physicians, cardiologists, surgeons and experts in healthcare from Pune and rest of Maharashtra and focuses on latest medical therapies, guidelines, case based discussions and cutting-edge technologies.

"There are approximately 10 million patients having reasonable affordability with cardiovascular diseases in India but only about 20% receive appropriate treatment. Our idea is to bring together experts in the field of healthcare and make them aware of the healthcare delivery chain to address the market need holistically. This is achieved by way of spreading awareness and educating the medical practitioners about the technological advancements, timely diagnosis, post-surgery patient care and follow up for better outcomes," said Shamik Dasgupta, vice president, cardiac and vascular group, India Medtronic.

6. [Indian pharma firms build a war chest for acquisitions](#) – Mint

July 3, 2015: Mumbai: Indian drug makers are readying a war chest to fund acquisitions that will help expand their product range, and give them access to new markets and distribution networks at home and overseas, their appetite having been whetted by a string of recent purchases. In fact, just four companies—[Lupin](#) Ltd, Cadila Healthcare Ltd, [Aurobindo Pharma](#) Ltd and [Torrent Pharma](#)ceuticals Ltd—have lined up plans to raise a combined Rs.22,600 crore through qualified institutional placements (QIPs), or sales of shares and other securities to institutional investors.

"Almost two-thirds of the fund-raising by pharma companies will go towards funding acquisitions," said [Vrinda Mathur](#), a partner at [Grant Thornton](#) India Llp. "These acquisitions will be a mix of domestic companies—those with a strong product portfolio or with US Food and Drug Administration (FDA)-approved facilities—and international firms," Mathur added. On Thursday, Lupin acquired Russia-based [ZAO Biocom](#), entering a country that will be one of the top eight markets for drug makers by 2018, it said in a statement to BSE. Lupin did not disclose financial details of the transaction.