Daily News Monitor

30 May – 1 June 2015

IPR & Innovation

India's patent laws fully WTO compliant: Sitharaman, Business Standard **(31st May 2015)** India has a robust legal framework and it has always been on the side of the law with regard to intellectual property right (IPR) matters and fully compliant with WTO on the issue, Commerce Minister Nirmala Sitharaman said on Saturday. "It is pure misinformation that India has poor protection for intellectual property. India has a robust legislative framework and any company holding a patent is well-protected," she said on the programme "Talkathon", a new media initiative of the information and broadcasting ministry telecast live on Saturday evening.

Similar reports have appeared in:

India Today

Zee News

The Statesman **(1st June 2015)**

Access to Healthcare

Ananth Kumar: Will make North-east pharma hub; Centre to set up generic medicine centres in Assam, The Economic Times **(30th May 2015)** The centre is planning to sign a memorandum of understanding (MoU) with the Assam government to set up generic centres at about 100 hospitals in the state to provide generic medicines at very low cost to poor patients, Union Minister Ananth Kumar said today. "We want to sign a MoU under my ministry's Janaushadhi scheme and provide more than 500 generic medicines by setting up generic centres at about 100 hospitals in district and subdivisional headquarters", Union Minister for Chemicals and Fertilisers Ananth Kumar said after laying the foundation stone of National Institute of Pharmaceuticals Education and Research (NIPER) campus here. The Centre would set up the generic centres at the cost of Rs 2.5 lakh each in the state and the cost of 100 hospitals would be Rs 100 crore, he said.

Similar reports have appeared in:

Business Standard

Yahoo! News

The Times of India **(31st May 2015)**

The Telegraph **(31st May 2015)**

Ethics & Compliance

Vigilance to keep vigil on health officials, says Vij, The Tribune **(30th May 2015)** Senior officers, doctors and other functionaries of the Health Department in Haryana will now work under the watchful eyes of the State Vigilance Bureau (SVB). Health Minister Anil Vij said here today that he was perhaps the first minister in the country to ask the SVB in writing to keep watch on the activities of officials of his own department to end corruption. Vij said his instructions had started showing results as a Senior Drug Control Officer of the Food and Drug Administration was recently caught by the SVB for taking a bribe from a chemist.

PSM India recognizes Gujarat FDCA for excellent role of its XLN software in ensuring public safety, Pharmabiz.com **(30th May 2015)** The Gujarat Food and Drug Control Administration (FDCA) was recognized by Partnership for Safe Medicines (PSM) India for using innovative technological methods to ensure patient safety. The award was conferred to the state drug regulatory agency for developing its revolutionary self-licencing software Xtended Licensing and Laboratory Note (XLN) and using it effectively to adopt good governance in the regulatory system to raise its standards. This software, an integral part of the e-governance programme adopted by the Gujarat drug authority has been successful in regulating the sales and manufacturing aspects related to drugs, food and cosmetics; issuance of licenses, etc. One of the most important

features of this software is that it enables the registration of all the pharmacists and chemists within the state which prevents multiple illegal enrollments of pharmacists, a grave issue that regulators have to tackle with today.

Medical & Regulatory

Health ministry moots online sale of drugs; regulator works on guidelines, The Times of India **(30th May 2015)**
As online shopping catches up, you could buy medicines too with a click of the mouse for which the health ministry is evaluating a proposal. The drug quality regulator is framing guidelines and mechanism to monitor such sale. The proposal is expected to be taken up for discussion in the drugs consultative committee meeting next month, a senior regulatory official said. At present, the Drugs & Cosmetics Act does not allow sale of Schedule 'H' medicines without a doctor's prescription. In fact, even over-the-counter (OTC) pharmaceutical products can be sold only by licensed retailers. However, lately various cases were reported to the central drug regulator in which online retail platforms were found selling medicines. In the absence of guidelines, regulatory agencies are finding it difficult to track and monitor such sale.

Antibiotic-resistant superbugs cast a dreaded spell, The Hindu Business Line **(30th May 2015)**
In 2010, an international study that traced a drug resistant “super bug” strain of bacteria to New Delhi, after which it was named, had the Government in a flap. There was denial from the Government that the Indian subcontinent was the source of this superbug. And there was rage - conspiratorial motives were alleged including a plot to destabilize India as a destination for medical tourism. While the truth may be somewhere in between, there certainly was a silver lining to this NDM-1 super bug controversy. It put the spotlight on antibiotic resistance, a live and ticking bomb. Resistance happens when bacteria adapts and antibiotics are no longer effective in treating infections caused by them. Simply put, a wound with a bad bug could kill, because even the strongest antibiotic fails to work on the body.

110 Med Shops Booked for Skin Cream Sale, The New Indian Express **(30th May 2015)**
The Telangana Drug Control Administration officials found 110 medical shops across the state selling skin creams containing steroids. DCA Director Akun Sabharwal said raids were carried out over the last two days to curb the sale of skin creams containing steroids or other combinations without a valid prescription. “As many as 110 chemists across the state were found indulging in this illegal practice. Cases under Section 65 of the Drugs & Cosmetics Act have been registered against them,’’ he said. Some of these harmful skin creams are skin light cream, Melacare cream, Look brite cream, Lumaglo cream, Melalite 15 cream and Panderm+. Four medical shops each in Secunerabad, SR Nagar and Rajendranagar, three each in Gowliguda, Jeedimetla and Chikkadpally, five in Malkajgiri, two in Hayatnagar and one in Saroornagar were found guilty.

DCGI urged to issue norms on printing expiry dates on tubes containing ointments & creams, Pharmabiz.com **(30th May 2015)**
The Indian Drug Manufacturers Association (IDMA) has urged the office of DCGI to issue necessary guidelines with regard to printing of manufacturing and expiry dates on tubes containing ointments and creams. Currently pharma companies marketing ointments in tubes are printing only manufacturing dates with a text stating expiry after a period of 24 months or 36 months. The issue has come up after a few members informed IDMA about the drug inspectors raising objection for not printing expiry dates on tubes in plants of these members. Inspectors declared the products without expiry dates are misbranded and have also instructed the manufacturers to print or emboss both the date of manufacture and expiry.

Tamil Nadu DCA gets prestigious award ‘State with Best Enforcement of Drugs Laws’, Pharmabiz.com **(30th May 2015)**
Appraising the strong law enforcement activities being carried out in Tamil Nadu, the state drugs control department has been conferred with the prestigious award, ‘State with Best Enforcement of Drugs Laws’ by the New Delhi based national NGO, Partnership for Safe Medicines (PSM) India Initiative. The award given for strict enforcement of Drugs and Cosmetics Act and Rules was received by the state drugs control director, S Abdul Khader, at the 5th National Conference of PSM held at Gandhi Bhawan, University of Kashmir, in Srinagar on May 20. PSM organised the conference and award function in collaboration with Government of India and the University of Kashmir. Dr G N Singh, DCGI, Asiya Naqash, health minister of J&K, Prof Khurshid Iqbal Andrabi, vice-chancellor of Kashmir University and drugs control directors from various states were present in the meeting.

Maharashtra FDA issues notices to e-cigarettes sellers, The Times of India **(31st May 2015)**
The state Food and Drug Administration (FDA) issued notices to 23 importers and sellers of e-cigarettes in Mumbai for violation of the Drugs and Cosmetics Act. The department has observed that use of e-cigarettes that contain nicotine, much like real cigarettes, is on an exponential rise mainly among youngsters. FDA Maharashtra issued notices to importers, distributors and dealers of e-cigarettes under Drugs and Cosmetics Act. The officials clarified that permission to sell lozenges or gums containing less than 2mg nicotine (are already given by Drugs Controller General of India. However, nicotine products above 2 mg are supposed to be sold only when prescribed by a registered medical practitioner.

Similar reports have appeared in:

The Economic Times

Business Standard

DNA India

Press Trust of India

Health ministry moots a proposal for online sale of medicines, The Economic Times **(31st May 2015)**
As online shopping catches up, you could buy medicines too with a click of the mouse for which the health ministry is evaluating a proposal. The drug quality regulator is framing guidelines and mechanism to monitor such sale. The proposal is expected to be taken up for discussion in the drugs consultative committee meeting next month, a senior regulatory official said. At present, the Drugs & Cosmetics Act does not allow sale of Schedule 'H' medicines without a doctor's prescription. In fact, even over-the-counter (OTC) pharmaceutical products can be sold only by licensed retailers.

Sale of electronic cigarettes labeled illegal in Maharashtra, The Times of India **(1st June 2015)**
Sale of electronic cigarettes (e-cigarettes) containing nicotine has been officially labeled 'illegal' in Maharashtra. To rein in the rampant use of the battery operated device which is currently available everywhere from departmental stores to paan shops, the state Food and Drug Administration (FDA) has issued show-cause notices to its importers, distributors and dealers for selling the product without mandatory permission from Drug Controller General of India (DCGI) which is in direct contravention of Drugs and Cosmetics Act and makes the trade illegal.

Price monitoring cells of NPPA yet to come up in state Drug Control Depts, Pharmabiz.com **(1st June 2015)**
Although National Pharmaceutical Pricing Authority (NPPA)'s discussed and proposed a plan to set up price monitoring cells for effective detection of drug price violations in all the states three months ago, no state in the country has come up the with the NPPA cell due to no fund allocation from the Centre among other issues. As per the plan, the drug pricing regulator aims to set up dedicated administrative cells within the offices of each of the state drug departments across the country. While the expenditure related to manpower, amenities and other infrastructural cost will be borne by the NPPA, state government will have to provide the space for setting up the office within the state drug regulatory office.

Other News on Pharma

DCGI urged to ban Power Morcellator used in hysterectomy as it causes cancer, Pharmabiz.com **(30th May 2015)**
In a letter sent to Dr G N Singh, the drugs controller general of India, the professor of pharmacy at the Birla Institute of Technology in Ranchi and former chairman of the Hospital Pharmacists Association, Dr Roop Narayan Gupta, wanted him to ban the medical device, Power Morcellator, used in hysterectomy or uterus removal as studies show that its use leads to dissemination of malignant tissue. Dr Gupta's letter mentions that there is crystal clear evidence in research studies which reveal that this surgery tool can spread hidden uterus cancer. Considering the study report, the use of the device should be banned in India or restricted with immediate effect.

Karnataka pharma cos upset over hefty price hikes for antibiotics, other APIs imported from China, Pharmabiz.com **(30th May 2015)**
Karnataka pharma industry is facing a dual challenge of hefty price hike and short supply of active pharmaceutical ingredients (APIs) like sucralfate, pantoprazole, ibuprofen, menthol, fluoroquinolones and vitamin C. The shortage of antibiotics, analgesics and other APIs, imported from China, is critical for formulation companies including Micro Labs, Bal Pharma and Embiotic. The price hikes of these APIs

have been going on for one year now: Sucralfate price increased from Rs.400 a kg to Rs.1,000 indicating a 150 per cent rise. Pantoprazole is up by 87.5 per cent from Rs.4,000 to Rs.7,500. Menthol is 66.6 per cent from Rs.900 to Rs.1,500. Ibuprofen is up by 29 per cent from Rs.550 to Rs.710. Ofloxacin went up by 42.8 per cent from Rs.2,100 to Rs.3,000. Levofloxacin reported 66.6 per cent increase from Rs.1,800 to Rs.3,000. Vitamin C price went up by a 40 per cent. There has been a steady increase of price of 30 to 40 per cent for fluoroquinolone which are a broad spectrum of antibiotic in one year, Harish K Jain, treasurer, KDPMA and director, Embiotic Laboratories, told Pharmabiz.

Medical devices industry urges Centre to set up core committee to act on task force proposals, Pharmabiz.com **(30th May 2015)**
The medical devices industry has demanded the Central government to set up a core committee consisting of joint secretaries from the commerce ministry, ministry of health, department of pharmaceuticals (DoP) and DIPP. The main aim behind this demand is to ensure that these officials from the core committee will act as the drivers to finally implement the recommendations of the task force. A delegation of the medical device industry recently met DoP secretary in this connection. Experts from the industry state that they have been forced to take this steps as there has been no initiative by the government to act upon the task force recommendations. Apart from this, they also insisted that these recommendations need to be approved by the cabinet so that the ministries responsible to take a call on these recommendations can finally put their act together.

New inorganic route, Financial Chronicle **(31st May 2015)**
With the last couple of years being challenging for the pharmaceutical sector in the country because of adverse actions of the US food and drug administration (USFDA), the series of announcements in the recent quarters and acquisitive drive of companies to broaden their portfolio have improved the overall sentiment. The companies are also looking at various opportunities presented in the specialty segment and around $4 billion opportunity in the US alone for the abbreviated new drug development applications (ANDA).
