

## IPR & Innovation

### India's IPR environment is maturing, [The Hindu Business Line](#) (23 May 2015)

The establishment of the World Trade Organisation (WTO) at the conclusion of the Uruguay Round (UR) on negotiations in 1995 signalled a quantum leap in integrating developing countries with the global economies. Developing countries undertook greater commitments lured by additional market access in agriculture, textiles and the movement of people. In a well-researched report by RIS India, the gains from the UR proposals were estimated to be between \$213-\$510 billion a year, with developing countries benefiting to the tune of \$86-\$122 billion. Empirical evidence suggests that there has been a significant deviation of these income flows to the developing world in favour of the developed world.

### Chennai patent office rejects Merck arm's plea for female contraceptive, [Financial Express](#) (23 May 2015)

NV Organon, a subsidiary of US-based Merck & Co — one of the largest pharma companies in the world — has failed to secure a patent in India for its invention on a female contraceptive kit. The kit, which comprises a vaginal ring, is used in cyclical dosage and has a reminder system. Organon has a similar product under trade name NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), which received initial US approval in 2001 and has been marketed worldwide.

## Access to Healthcare

### Global funding dips by 90%, may cripple war on AIDS, [The Times of India](#) (23 May 2015)

International funds for India's National AIDS Control Programme have dried up severely, posing a serious threat of recurrence of new HIV cases. Estimates show a reduction of almost 90% in funding from various multilateral, bilateral and philanthropic donor organisations over the last three years, sources in the government as well as civil society said. While many multilateral organisations, including World Health Organisation (WHO) and several UN agencies such as UNICEF and United Nations Development Programme (UNDP), have either drastically scaled down or diverted funds from India's HIV control programme to other countries, bilateral and even philanthropic donor organisations like Bill & Melinda Gates Foundation, Clinton Health Access Initiative and World Vision have slashed funding to the national programme.

### After polio, India set to win battle against tetanus at childbirth, [The Indian Express](#) (24 May 2015)

A year after obtaining WHO certification for the elimination of polio, India is on the verge of crossing another milestone in public health. It has eliminated maternal and neonatal tetanus — an infection that at its peak killed an estimated 2 lakh adults and children every year — and is expecting an official certification from WHO within two months, Health Ministry sources told The Sunday Express. Confirmation of the breakthrough came after a joint team of WHO and UNICEF recently conducted field visits in Jammu and Kashmir, Nagaland and Meghalaya, and Dadra and Nagar Haveli, which were the last four hotspots where incidence of the infection had remained above acceptable levels, sources said.

### Health check-up camp, [The Tribune](#) (25 May 2015)

A free health check-up camp was organised at the Chander Nagar dharamshal by the Anti-Crime Front Against Corruption. A team of doctors from SPS Apollo Hospitals examined the patients. Dr Sanjeev Kumar Mittal, Dr Dhiraj and Dr Vishal Patel apprised the patients of the factors causing heart diseases and advised them to take medical advice on time. A group of doctors and people from various walks of life have launched the Manavta Health Mission to render healthcare services and spread awareness on government policies and infrastructure related to health. At the inaugural function, a public seminar was held which covered topics like comprehensive healthcare, draft nutritional health policy, the status of women in society and health insurance. Speaking on the occasion, Dr Narjit Kaur, Dr Anakhveer Gill, Dr Arun Mitra and others said the mission would work for the delivery of affordable healthcare to all and mobilise public opinion for a suitable increase in health budget.

## Ethics & Compliance

### **IMA 'Kent' endorse. Or can it?, [The Times of India](#) (23 May 2015)**

The Indian Medical Association seems to be tying itself up in knots trying to justify the advertisements for Kent water purifiers stating that the association has 'validated' its water purifier the product. These advertisements have raised the issue of doctors' associations endorsing commercial products. The Medical Council of India's (MCI) code of ethics forbids doctors from endorsing any commercial products. But IMA argued that while individual doctors could not, medical associations could. It also insisted that this was not an endorsement, but a 'public campaign' titled 'safe water prevents waterborne diseases'. IMA secretary general Dr K K Aggarwal also claimed not to know how much Kent was paying the association for the 'campaign', and said he would find out from the find out from IMA's standing committee on finance.

### **Loopholes in law renders medicinal cross practice unchecked, [The Times of India](#) (25 May 2015)**

The idiom 'who will bell the cat?' fits the bill when it comes to non-allopathic doctors prescribing allopathic drugs. The trend, though less prevalent in Goa when compared to neighbouring Maharashtra, is causing quite a stir with a significant number of ayurvedic and homeopathic doctors openly prescribing allopathic medicines. The food and drugs administration (FDA) and chemist and druggists association, Goa (CDAG) have raised an alarm, but only strong action by the government can put an end to illegal or cross practices by some ayurvedic and homeopathic physicians, say pharmacists.

## Medical & Regulatory

### **Pharma firms evade NPPA database, [Asian Age](#) (23 May 2015)**

The Ingredient Pharmaceutical Database Management System (IPDMS) launched in September last year by the National Pharmaceutical Pricing Authority (NPPA) is yet to see the light of the day with a majority of pharmaceutical manufacturers yet to enrol themselves on the online portal. Despite repeated reminders and warnings since last year, 32 companies are yet to enrol themselves under the programme. These include, as per the NPPA list, big names such as Ranbaxy Laboratories Limited, Dabur India Limited, Zydus Cadila, Alkem Laboratories Limited, Himalaya Drug Company, Hetero Laboratory Limited and Wockhardt Limited, in addition to 27 others. The delay has been witnessed despite the NPPA having extended the registration dates two times since last year. Warnings have been issued along with notices clearly stating that failure to enrol will attract penalties and punishment under the Essential Commodities Act 2005.

**Seminar held to address myths, regulatory issues on PET packaging for pharma products, [Pharmabiz.com](#) (23 May 2015)**

Indian Regulations allow PET for pharma packaging under Drugs & Cosmetics Act (1940), Schedule M, Section 16.10. Stability studies and also under Drugs & Cosmetics Rules (1945), Schedule M, para 11 pharmacopoeial compliance. It is also stipulated for use under Indian Pharmacopoeia in IP 2010, General Chapter 6.2.3 and under Bureau of Indian Standards for use in contact with foodstuffs, pharmaceutical and drinking water. Several other Indian standards also exist to control and allow PET containers for pharma packing. These were some of the points drawn during a national level seminar on 'PET Packaging of Pharmaceuticals' held recently in Mumbai organized by PET division of Reliance Industries Ltd (RIL)- RelPet. This seminar had presentations from RIL, HCA (colorant supplier) and ASB (machinery manufacturer) among others.

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**Buying drugs over the counter? You need a prescription if US has banned them, [Hindustan Times](#) (23 May 2015)**

If the drug you consume is banned in US, UK, Canada, Japan, European Union or Australia, you may need to get a new prescription. The government is streamlining the drug regulatory system to filter drugs with serious side effects, based on their ban status from six major drug regulators globally. For instance, Analgin, a pain killer, was banned in the US and Sweden in the late 1990s as it triggered a sharp fall in white blood cells, but is still sold in India. Henceforth, such drugs would not be sold here until clinical data proves them safe. The move was triggered after the government learned about Danish firm Lundbeck's anti-depression drug Deanxit, which is banned in Denmark but allowed to be exported.

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**E-commerce website booked by FDA for selling Schedule H drugs, [The Indian Express](#) (24 May 2015)**

The state branch of Food and Drug Administration (FDA) last week filed an FIR with the Panvel Police station against e-commerce website shopclues.com's CEO Sanjay Sethi stating that the web portal sold medicines, including ones used for contraception that compulsorily require a prescription of a medical practitioner. This is the second website to come under the scanner this month after e-commerce giant Snapdeal was booked for selling Schedule H drugs on May 1. The case at Panvel police station has been filed under sections 23 (3), 28, 27 (b) of the Drugs and Cosmetics Act, 1940, in addition to Section 7 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

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**Pharma cos demand UCPMP to be industry friendly, [Pharmabiz.com](#) (25 May 2015)**

The pharma companies have approached the Department of Pharmaceuticals (DoP) and the Medical Council of India (MCI) to make the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) industry friendly. The UCPMP restrained the healthcare professionals from accepting free samples, gift, traveling facilities, cash or monetary benefits from pharmaceutical companies. So, the pharma companies especially SMEs and new entrants fear that the new marketing code may affect branding of their products and with no alternative sources of visibility and information among the medical professionals. At present the UCPMP is to be voluntarily adopted by pharma companies with effect from January 01, 2015 for a period of six months and the Department will be reviewing the compliance record during the period on the basis of inputs received. DoP has also directed the pharma association to form a complaint handling committee named as 'Ethics Committee for Pharma Marketing Practices' for the proper implementation of UCPMP.

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**DoP directs NPPA to revise prices of frusemide, phenarmine maleate & frusemide under para 4(1) of DP, [Pharmabiz.com](#) (25 May 2015)**

The Department of Pharmaceuticals (DoP) has directed the National Pharmaceutical Pricing Authority (NPPA) to revise the prices of frusemide 10 mg/ml injections, phenarmine maleate injection 22.75 mg/ml and frusemide 40 mg tablet under para 4(1) of DPCO, 2013 and not under para 6. The DoP was acting on review applications filed by Sanofi Ltd against the fixation/revision of ceiling prices of these medicines. Earlier, the NPPA vide its notification S.O. No. 2360(E) dated 15/9/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013) had fixed/revised ceiling price of frusemide 10 mg/ml injections, phenarmine maleate injection 22.75 mg/ml and frusemide 40 mg tablet. Aggrieved by the notification, Sanofi submitted review applications dated 13.10.2014 under para.31 of DPCO, 2013 for the review of NPPA price fixation order S.O.No.2360 (E) Dated 15.9.2014.

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**DoP move to promote bulk drugs industry may reduce prices of medicines in future: S V Veeramani, [Pharmabiz.com](http://Pharmabiz.com) (25 May 2015)**

The move of the Department of Pharmaceuticals (DoP) to promote Indian bulk drugs industry to boost the pharmaceutical sector may help reduce the prices of medicines in the domestic market in the long run, according to S V Veeramani, president, Indian Drugs Manufacturers Association (IDMA). In an interview with Pharmabiz, he said the efforts of the DoP will be very valuable in reducing dependence on China for supply of bulk drugs. On a long term basis, this will reduce the monopolistic situation created by supplies from China to greater self-reliance of India. If this happens, it can reduce the prices of medicines in the domestic market.

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**IV fluid makers get NPPA warning, [DNA India](http://DNA India) (25 May 2015)**

The National Pharmaceutical Pricing Authority (NPPA) in its recent notification reminded the manufacturers and marketing companies of IV fluids to submit price-to-retailer (PTR) and moving annual total (MAT) value for September 2013, saying non-compliance may lead to the regulator taking appropriate action. This is the third time NPPA has made a request to the manufacturing and marketing companies to provide the required data. In its notification, NPPA said that its office has not received requisite data or information along with copy of supporting invoices from all concerned manufacturing and marketing companies of IV fluid as sought for office memorandum dated March 4, 2015 and reminder dated March 27, 2015.

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**PSM advocates strong Centre-state network for effective infra support for drug depts., [Pharmabiz.com](http://Pharmabiz.com) (25 May 2015)**

Partnership for Safe Medicines, asserts the need for a strong network between the Central and State governments to put in place infrastructure for drug test labs, computerization and ensure adequate staffing of drug inspectors. Currently, there exists a huge gap between states and the Centre in drug regulatory systems. It is important to put in place a mechanism because to provide the much needed transparency and effective supply chain process. This should also be supported with the adequate infrastructure like the drug test labs and adequate presence of drug inspectors, Bejon Mishra, founder and chief Partnership of Safe Medicines (PSM) told Pharmabiz.

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**Upbeat economy apart, cuts in social sector pinching common man, [DNA India](http://DNA India) (25 May 2015)**

Union finance minister Arun Jaitley's assessment of an upbeat economy, notwithstanding, a year after the NDA government assumed office heavy cuts in the social sector expenditure is pinching the common man on ground. In Rajasthan's Bharatpur district, the village dispensaries no more distribute free medicine. In Bihar and Jharkhand, a large number of villagers who worked under Mahatma Gandhi National Rural Employment Guarantee Act (MGNREGA) scheme have not been paid wages for over a year now. Even the economically prosperous states such as Maharashtra and Rajasthan are reporting either closure or merger of primary schools for want of funds. Against its promise to increase public expenditure on health from 1.2 % of gross domestic product (GDP) to 2.5 %, there are cuts in health ministry-related fund transfers to states from Rs 24,203 crore to Rs

18,000 crore. "The current government has adopted a disastrous go slow policy for increased and effectively using the health budget," says lawyer Menghaney, working on public health sector schemes. Dr Abhay Shukla of Jan Swasthya Abhiyan believes that in such a situation, private hospitals will flourish, since most of the population will continue to experience inadequate public health service.

## Other News on Pharma

### **USP workshop in Hyderabad to focus on improving quality of medicine, [Pharmabiz.com](http://Pharmabiz.com) (23 May 2015)**

The United States Pharmacopoeial Convention (USP) workshop scheduled to be held in Hyderabad from 26-28 May, is expected to focus on quality control and improving standards of medicines. The 3 day workshop at USP's campus in Hyderabad is expected to bring together national medicines control laboratory officials on improving aspects of medicines quality and highlight contemporary issues pertaining to quality aspects prevailing in Asia Pacific region and suggest ways and means for improving the quality of medicine standards.

### **Four of 10 stents used locally 'made in India', [The Times of India](http://The Times of India) (25 May 2015)**

Mention stents, and an image of an imported medical device with a hefty price tag comes to mind. But the latest data from the Cardiological Society of India shows that a sizeable number of stents - tiny, mesh-like tubes that are used to open up narrowed diseased arteries - used across hospitals in 2014 carried the 'Make in India' label. Almost four out of every 10 stents used in Indian hospitals carry a local tag, said the National Interventional Council (NIC) registry maintained by the CSI. "The Indian stents offer a price advantage," said a doctor. Only 396 out of the 624 cath labs (where stenting is carried out) across India report to the registry, but it provides the best insight into heart-care and disease patterns across the country.

### **Government must regulate pricing of stents: Doctors, [The Times of India](http://The Times of India) (25 May 2015)**

Desi stents are making its way into Indian hearts as they carry a price advantage. But then there are many doctors who still prefer to use foreign stents, even for poor patients. "A poor patient can never get what is considered the iPhone 6, but let us at least give him or her an iPhone 4 that has great amount of data and research behind it," said Dr Prafulla Kerkar, who heads the cardiology department of KEM Hospital in Parel. Stents, like smartphones, come with various upgrades and are named as 'generation 1', 'generation 2' and so on. The Maharashtra government procures drug-eluting stents costing between Rs 23,000 and Rs 28,000 for patients operated under its health schemes.