

## IPR & Innovation

### **Focus on data privacy laws to boost medical outsourcing, [The Economic Times](#)**

The government should introduce proper regulations for intellectual property and patents besides focusing on implementing data privacy laws to boost medical process outsourcing (MPO) sector, a study said today. In order to fuel growth in MPO sector, the Assocham-EY study suggested the government to "focus on implementing data privacy laws, introducing proper regulations around intellectual property and patent laws, and give a boost to education to help bridge the skill gap". Although, Indian regulatory environment has been constantly evolving, the challenges around privacy laws, intellectual property laws and changing clinical trial laws continue to exist, it said.

#### **Similar reports have appeared in:**

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### **Innovation, tech key factors for pharma sector in emerging markets, [The Economic Times](#)**

Innovation and technology will be important differentiators as pharma companies try to drive growth in emerging markets that face rapid growth of various chronic diseases like diabetes, hypertension, heart disease, and cancer, according to a report. Emerging markets are predicted to account for a third of global pharmaceutical spend by the end of next year and seen as critical for the sustained growth of leading pharma companies, the report by Cambridge Consultants said. Innovation and technology are key to growth for pharma companies in emerging markets, the report said.

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### **India, Brazil cross swords with U.S. at WTO – [The Hindu](#)**

#### Moratorium on Intellectual Property Complaints

Switzerland and the U.S. have begun a campaign at the World Trade Organisation (WTO) to not renew a moratorium on 'non-violation complaints and situations' for intellectual property rights that expires at the end of the year.

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### **Recent developments in intellectual property laws in India- Part 1, [The Economic Times](#)**

After the new Narendra Modi led Government took over the governance in the year 2014, there has been considerable debate and expectation, nationally as well as internationally, with respect to a more refined and developed intellectual property rights ("IP") law regime in India.

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### **Recent developments in intellectual property laws in India- Part 2, [The Economic Times](#)**

Besides to the most recent developments, in order to bring progressive changes towards a free market society, rapid liberalization of international trade practices and demonstrating its commitments to the WTO under the Trade Related Intellectual Property Rights Agreement (TRIPS), the Government of India

undertook a series of steps, to conform India IP legislation to acceptable international standards. The regulations relating to all forms of IP have been amended or reissued in recent years, mainly in response to India's accession to the WTO. Here are some of these developments in IP legislation in India.

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## Access to Healthcare

### **The healthcare challenge in India** [Business Standard](#)

India, since Independence, has achieved modest success when it comes to some aspects of public health, but much remains to be done for the future. At the time of Independence, the life expectancy at birth for an individual in India was 32 years, it has more than doubled to 66 years in 2013. Similarly, the infant mortality rate (IMR or the number of babies who die before their first birthday in a given year per 1,000 live births in that year) has gone down from 164 in early 1950s to 40 in 2013. Similarly, India has been able to eradicate polio and on March 27, 2014 was officially declared polio-free by the World Health Organisation. India also has in the past been able to eradicate diseases like smallpox. The story of change has been overall encouraging but still much more remains to be done. International comparisons immediately raise concerns about the how badly broken our public health system is.

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### **Recognise Anaemia as Public Health Challenge,** [The New Indian Express](#)

The frightening results of the latest district-level health survey, revealing that 49 per cent of women in Tamil Nadu are anaemic, should have by now rung the alarm bells in the Union health ministry. For, this could well be the case, or even worse, in other states, too. Though women's health has always been low on the priority list of Indian families and communities, letting the anaemic population grow does not augur well for the nation's public health initiatives.

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## Medical & Regulatory

### **Ananth Kumar releases report on enabling private sector to lead growth of pharma industry,** [Express Pharma](#)

The Union Minister of Chemicals and Fertilisers, Ananth Kumar has released task force report on enabling the private sector to lead the growth of pharmaceutical sector. The minister said that the government wants to encourage a robust pharma industry in the country that is upgraded, standardised, innovative, globally competitive and can produce formulations at affordable costs. He said in this regard, setting up of the task force was one of the major initiative of the government. To provide thrust to the sector, a task force on enabling the private sector to lead the growth of pharma sector was set up by the Department of Pharmaceuticals. The task force was headed by secretary, Department of Pharmaceuticals and consisted of representatives from Planning Commission, Department of Industrial Policy and Promotion, Department of Science and Technology, Department of Biotechnology and various Industry Associations including IPA, IDMA, BDMA, **OPPI**, AIMED, CIIO, FICCI, ASSOCHAM, FOPE etc. The task force has recommended measures to enhance regulatory support; suggested strengthening of infrastructural support; and recommended fiscal and financial support to the sector.

#### **Similar reports have appeared in:**

[Pharmabiz.com](#)

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### **Single-window clearance for pharma sector on anvil: Union Minister Ananth Kumar,** [DNA India](#)

To enable a single-window clearance system in pharmaceuticals sector, the government will set up a high-level committee next week to work out the modalities for the same. The committee will be headed by Pharmaceuticals Secretary V K Subburaj and the move follows a recommendation by the task force on enabling the private sector to lead the growth of the pharmaceuticals sector. The industry would be represented by Indian Pharmaceutical Association (IPA), Indian Drug Manufacturers Association (IDMA), Bulk Drug Manufacturers Association (BDMA), Association of Indian Medical Devices Industry (AIMED), CII, FICCI, ASSOCHAM and others.

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### **Homeopathy industry seeks statutory body for clinical trials,** [Business Standard](#)

In a bid to promote research and innovation of drugs, the homeopathy industry now seeks an independent statutory body that would have sufficient jurisdiction to sanction new clinical trials. According to Rajesh

Shah, director of Homeopathy India Foundation, while the Drug Controller General of India (DCGI) is supposed to look after homeopathic medicines too, there is no clarity or no clear mechanism that would approve a new drug discovery. "There is also no adequate infrastructure in the country at the moment that would encourage and support homeopathic research. As a result, not many new homeopathic medicines have been discovered in the last century," he claimed.

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#### **Fake drugs market taking shape of organised crime: CBI, [Business Standard](#)**

Fake drugs market in India is taking shape of transnational organised crime which may adversely affect the economy, CBI Director Anil Sinha said here today. Rs 27.6 crore fake drugs market may not be an alarming situation but it cannot be ignored as it is slowly taking shape of a transnational organised crime, Sinha said here at the inauguration of the first Indo-French workshop on 'Combating Counterfeit Medicine'. "Under the aegis of Central Drugs Standard Control Organisation, a systematic study was carried out to assess actual extent of spurious drug circulation in India. It was concluded that the extent of spurious drug in retail pharmacy is only 0.046 per cent," the CBI Director said.

#### **Similar reports have appeared in:**

[Press Trust of India](#)

[Zee News](#)

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#### **From clothes to drugs: Is India prepared for the e-commerce leap?, [IBN Live](#)**

The surge of e-commerce in India has been a subtle one. The e-retail industry valued at around \$4 billion in 2009, is expected to touch a whopping \$17.5 billion by 2018, as per a recent study by a digital research firm, eMarketer. The changes are enthralling, especially for one of the fastest developing economies in the world, to prove its might in the global market. At the same time, it has disturbed the brick and mortar business in India, which fears losing its customers to the online market place. In the clutter meanwhile, doubts are now being raised whether the e-commerce bubble is doomed to explode. While the sector has been successful in luring international investor to pledge an investment of more than \$5 billion in 2014, none of the top e-commerce players in India are close to being profitable and fears are rife that the current model of discounting and marketing tactic will make e-commerce player defunct in the near future.

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#### **Reviving AYUSH, [Express Pharma](#)**

Regulatory woes continue to plague the AYUSH sector in India and hamper its progress despite measures to revive the traditional forms of medicine. Ayurveda or ayurvedic medicines, are one of the oldest forms of treatment which traces its origin to India. In ancient times, this form of medicine was largely practised by vaidyas, the equivalent of modern-day doctors. Other forms of traditional medicines such as unani, siddha and homeopathy too were commonly practised in the yesteryears.

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#### **ReDefining NSQ, [Express Pharma](#)**

India has highest number of US FDA approved manufacturing facilities outside the US and yet the Indian pharma industry faces issues of 'Not of Standard Quality (NSQ) drugs too often. These issues have affected the reputation of the Indian pharma industry adversely. Globally, the image of the Indian pharma industry is getting blurred due to various reason. Hence, the Department of Health, Ministry of Health and Family Welfare has decided to redefine 'Not of Standard Quality' drugs and proposed certain changes in Section 36AC. The industry and associations share their views on the changes proposed and their potential impact.

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#### **IPA wants Regulatory Affairs Science as academic discipline for higher education in pharmacy, [Pharmabiz.com](#)**

The Regulatory Affairs Division (RAD) of the Indian Pharmaceutical Association (IPA) wants Regulatory Affairs Science as an academic discipline and a research topic as part of higher education in pharmacy. In respect of this field of study, RAD is conceiving ideas from experienced drug regulatory officers, expert leaders of industry and prominent academicians, said Dr Subhash Mandal, chairman of RAD of IPA. He said PG and research programmes in Regulatory Affairs Sciences have developed in some western countries and several universities offer higher level academic programmes in the subject. In India, discussions are going on among experts to justify its status as an independent academic discipline in the pharmacy education. RAD will apprise the Union government and the office of the Drugs Controller General of India (DCGI) of the necessity of introducing.

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## Other News on Pharma

### **India to open drugs database to global regulators** [The Economic Times](#)

Drug regulators and retailers across the world will soon be able to access a large database that India is building on domestic pharmaceutical manufacturers. India has decided to throw open the database to global stakeholders following concerns over spurious drugs emanating from the country.

The government had earlier introduced barcoding on export consignments of medicines to help trace their point of origin.

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### **Healthcare and pharma industry will see a hike of about 11.5 per cent: TeamLease report** [The Financial Express](#)

There is an increasing demand for talent across sectors with employees expected to receive double digit salary growth, if the latest report by Teamlease is to be believed. Teamlease Annual Salary Primer, released recently, analysed a variety of attributes that govern the dynamics of the employment market – skills, salaries, increments and longevity (which is a measure of the time period for which a profile would stay in a job – the inverse of attrition).

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### **Govt may cap orthopaedic implant prices,** [The Economic Times](#)

Soon, there may be ceiling prices, fixed by the government, on orthopaedic implants. Alarmed with the sharp spike in prices of orthopaedic implants, drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has directed manufacturers — such as Johnson & Johnson (J&J), Zimmer and Stryker — to submit details of production and pricing of their products, including those for knee and hip. At present there are no price caps on these medical devices. The companies will also need to submit the increase in prices effected by them over the last three years, the NPPA communication on June 17 said.

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