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IPR & Innovation

'Make in India' and compulsory licensing, Pharmabiz.com

Make in India is bound to succeed with the powerful global initiative by the Prime Minister of India and his team. The latest amendment notification it has become all the more closer and faster to success. The **Organisation of Pharmaceutical Producers of India** members are vociferously against the compulsory licensing (successfully supported by USTR and Super 301 conditions and cautions). The IPA has publicly announced that IPA members prefer the voluntary licence route and hence will not opt for compulsory licensing. The fourth group of tiny and small pharmaceutical companies as well as large majority of IDMA (99 per cent) are not concerned with WTO, TRIPs or Compulsory Licensing. What is left is a mere 1 per cent of one of the four groups as above. They have neither the financial muscle power to fight long drawn out legal battles for compulsory licensing nor the political clout. With the newest amendment of “manufacturing in India” being interpreted to include “importing into India”, while make in India succeeds, the Section 84 (1)(c) provision of compulsory licence will forever remain unmet.

Access to Healthcare

Government proposal to provide affordable medicines faces roadblocks, The Hindu

The system should ensure medicines reach both the middle class and the poor who depend on the government healthcare sector. In a meeting on June 1, the ministry of chemicals and fertilisers had announced that it proposed to launch 1,000 stores in one day under a different name. The Central government’s ambitious proposal to provide affordable medicines through Jan Aushadi medical stores across the country would require thorough planning. The government’s plan is to launch 1,000 Jan Aushadi stores in a day, across the country. The previous efforts in the direction have not done well. Even at the trial stage expectations were belied.

Oral Cholera Vaccine is Effective, Could be Deployed in Endemic Regions, The New Indian Express

With oral cholera vaccine Sanchol proving its worth in population-based trials, experts have called for expeditious deployment in immunisation programmes in India and other endemic countries to prevent thousands of deaths every year. Sanchol has been as efficacious in real community situations as results reported from a clinical trial. The vaccine was found to have induced cholera protection against clinically significant cholera in around 70 percent of the people during population tests in an endemic area of Satyabadi block of Puri district in Odisha while in the clinical trials at Kolkata earlier the vaccine provided 65 percent protection over five years, a study has revealed.

Medical & Regulatory

DCGI for formulating framework for online sale of medicines, Business Standard

Drugs Controller General of India has called for formulating a framework for online sales of medicines through e-commerce channels. "The role, responsibilities and liabilities of e-commerce marketplace and the product sellers need to be clearly defined. "It becomes even more critical to have a framework in place when the intermediary is selling drugs where the safety and health of the consumer is of paramount importance," industry body Ficci's statement quoting Drugs Controller General (India) G N Singh said. The industry body said it has been appointed as the nodal agency by the DCGI for consolidating the guidelines and was to get views of **Organisation of Pharmaceutical Producers of India**, All India Chemists and Druggists Association, States Chemists and Druggists Associations, Indian Medical Association, among others, in this regard.

Similar reports have appeared in:

The Hindu Business Line

Government approves FDI worth Rs 4,000 crore by four pharma firms, The Economic Times

Proposals for foreign direct investment amounting to around Rs 4,000 crore by four pharma and medical devices firms, including Torrent Pharmaceuticals and Biocon's research services arm Syngene, were today approved by the government. The government, however, rejected proposal of drug firm Strides Arcolab to issue shares to non-resident and resident equity shareholders of Shasun Pharmaceuticals and deferred three proposals from other firms.

Similar reports have appeared in:

Business Standard

Financial Express

Outlook India

MoneyControl

Firstpost.com

Modi government to approve 6 pharma parks with Rs 180 crore investment, The Economic Times

Government is set to approve six pharma parks this year at an estimated investment of Rs 180 crore to promote the pharmaceuticals manufacturing. "This year the six pharma parks will be allocated on pilot basis and in the next year my ministry will seek Rs 1,000 crore from Finance Ministry for setting up of parks across the country," Fertiliser and Chemicals Minister Ananth Kumar said inaugurating the launch of "Cluster Development Programme of Pharma Sector here today. Kumar said out of the six parks to be allocated, three will be greenfield and remaining three will be brownfield. The Minister also mentioned that there will be sufficient infrastructure and facilities in these parks, for testing and treatment of drugs and also for imparting training to industry professionals.

Similar reports have appeared in:

Business Standard

The Hindu Business Line

DNA India

Zee News

Framework for Online Medicines Sale on Cards, The New Indian Express

The Drugs Controller General of India (DCGI) is working on a framework to facilitate online sale of medicines. The move comes amid concerns over sale of medicines on e-commerce portals. In April, Maharashtra's Food and Drugs Administration (FDA) raided Snapdeal.com for allegedly selling medicines, including prescription drugs. Similarly, notices were issued to pharmacy chains like Apollo in Telangana for selling drugs online. Currently, consumers are allowed to buy medicines only by uploading a doctor's prescription. They, however, have to personally visit the medical store to collect medicines as home delivery of medicines is against the rules.

Major healthcare associations collaborate to fight spurious drugs menace, Pharmabiz.com

Keen to combat the issue of spurious drugs menace, top professional healthcare groups across the country have recently come together to sensitise and bring in attention to this issue. The whole initiative was aimed at increasing awareness about the dangers of spurious medicines and how to efficiently identify and deal with the cases. World Health Professions Alliance (WHPA) is spearheading it in association with the Indian Pharmaceutical Association (IPA), the Indian Medical Association (IMA) and the Indian Council of Nurses (ICN). This collaborative effort, a first of its kind pilot project, emphasized on developing collaborative practice by all the healthcare professionals through training programmes on spurious drugs.

CDSCO shows tremendous progress in reducing regulatory approval time through its 'just-in-time', Pharmabiz.com

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n a move to enhance the drug regulatory system in the country, the Central Drugs Standard Control Organisation (CDSCO) has started full swing operation of its 'just-in-time' services. This unique service,

which basically focuses on providing on the spot regulatory approval for hastening the regulatory approval process for select categories, was initially flagged off few months back as a part of the new government's commitment to bring in transparency and efficient delivery of government services.

Other News on Pharma

Medical Devices Authority, Pharmabiz.com

The use of medical devices and diagnostics has grown exponentially in India over the last 20 years with the sharp rise in lifestyle diseases among all classes of people. Medical devices or implants are routinely prescribed by doctors for heart patients, kidney patients, people suffering from urological problems, those afflicted by a variety of orthopedic conditions, hearing problems etc. And almost 70 per cent of the medical devices in terms of value are being regularly imported into the country for years as the domestic industry did not register the desired growth rate and the units remained mostly small and medium scale operators. What is disturbing is the fact that the medical devices sector remained largely outside the purview of any regulatory control in India all these years despite the fact that these are life saving products. Taking advantage of this regulatory vacuum, there has been large inflow of not of standard quality products into the country with very high price tags. Patients requiring these devices have no option but go for them at whatever quality and price offered by the suppliers.

CPhI Pharma Awards 2015 open with five new categories, Pharmabiz.com

CPhI Worldwide has announced the opening of the annual CPhI Pharma Awards for 2015 – with five new categories covering the entire pharmaceutical supply chain. Now in their 12th consecutive year, the awards will honour companies and individuals driving the pharma industry forward through innovations, new approaches, technologies and strategies. This year's awards are open for entries from across the entire pharmaceutical industry and are split into eight categories covering: 'Best Innovation in Packaging'; 'Best Innovation in Process and Formulation Development'; 'Excellence in Partnering & Outsourcing'; 'Best Innovation in APIs and Excipients'; 'Best Innovation in Biologic Drug Development and Manufacturing; 'Innovation in Supply Chain & Logistic Management'; 'Best Innovation in Manufacturing Technology'; and 'CEO of the Year'.