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Biopolicy

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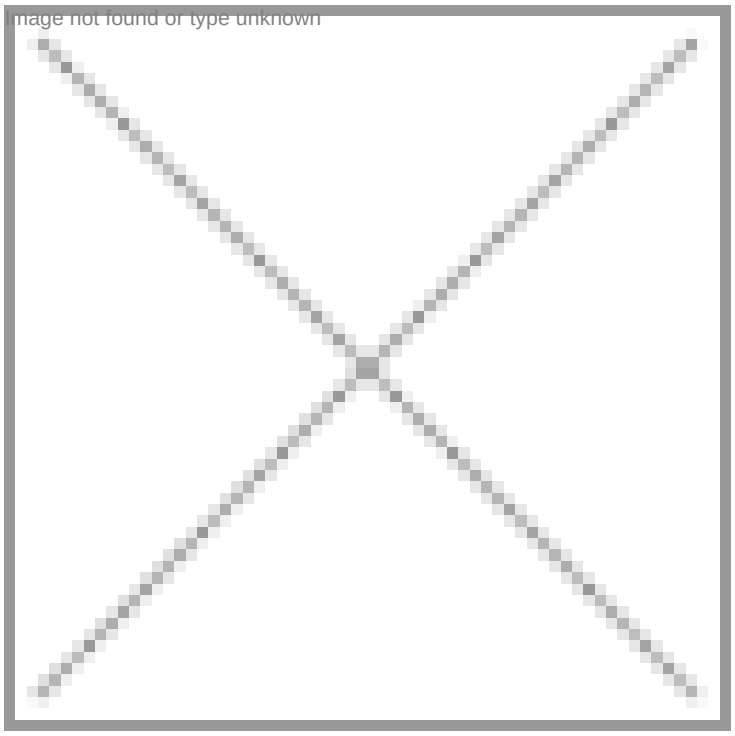


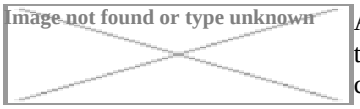
â€œThe government is mulling a proposal to allow foreign direct investment (FDI) in the pharmaceutical sector in the next few month's, said Saurabh Chandra, secretary of the Department of Industrial Policy and Promotion (DIPP) at the Associated Chambers of Commerce and Industry of India (ASSOCHAM) event held in New Delhi on August 29, 2012.

Earlier in July, an inter-ministerial panel had finalized the new FDI guidelines for the pharma industry, a move that was expected to clear the way for more than 3,000 crore worth of FDI proposals.

â€œThere is a need for the government and the industry in general to join hands to reverse the downtrend of industrial production index which has primarily been led by capital goods and decline in production of commercial value,â€? said Chandra.

Video consent, soon to be must for CROs

The Indian health ministry will soon amend the â€œSchedule Yâ€? of Drugs and Cosmetics Rules to make a provision for audio or video recording of the informed consent in clinical trials.



As per reports, once the necessary amendments are done by the ministry in this regard, the recording of informed consent will become mandatory in the country. Besides this, the procedure of providing information to the subject and his understood consent should be maintained by the investigator for record. Aimed at ensuring proper care for the clinical trial participant, the video consent will record that the subject has been well informed about the pros and cons of the clinical trial and participation is voluntary. This will also serve as a proof in case there is any trial death issue later on.

Govt to improve regulatory framework

â€œThe ministry of health is working on transparency and accountability to encourage all manufacturers to go for trials. The central government's 12th Plan will fund state regulators to strengthen their infrastructure and man power.â€? This was stated by Arun Kumar Panda, joint secretary, Ministry of Health and Family Welfare, Government of India at a conference - PharmTech 2012 held in New Delhi on September 14, 2012. Panda, who is responsible for drug regulation, spoke of conducting effective drug trials. Organized by PHD Chambers, the meeting brought together senior government officials, captains from Indian pharmaceutical industry and technical experts to present views on technology innovation and upgrade.

Experts delved into hot topics of the pharma industry including supply chain effectiveness, allotment of costs to R&D, drug control and inspection and FDI. The conclave witnessed discussions on subjects including intellectual property rights, FDI, business process re-engineering and R&D scale up among others.

Rajasthan halts GM mustard trial

The government of Rajasthan has recently conveyed its decision to withdraw the no objection certificate (NOC) which was issued to the Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi for the conduct of second season Biosafety Research Level trial with GM Mustard. The trials had been earlier approved by the Genetic Engineering Appraisal Committee (GEAC).

On perusal of the directions issued by the Government of Rajasthan, it was noted that no new facts regarding non-compliance of biosafety measures or evidence of harm have been cited as a reason which compelled them to withdraw their NOC.

Govt to set up drug controller office

The department of AYUSH, Ministry of Health and Family Welfare, Government of India, has proposed to set up a Central Drug Controller's Office for AYUSH drugs to enhance the acceptability and export of ayurveda, yoga and naturopathy, unani, siddha and homoeopathy (AYUSH). It will be headed by additional drug controller general of India (AYUSH).

The expenditure finance committee (EFC) chaired by the secretary has approved the proposal for creating 40 posts in the proposed Central Drug Controller's Office (AYUSH) for supporting engagement of 330 scientific manpower in the state drug testing laboratories. The matter for creation of required manpower is under examination in consultation with the department of expenditure and an allocation o 80 lakh is made in the annual plan 2012-13 for the purpose.

FDA APPROVALS & PATENTS

Cadista gets US FDA nod

Noida-based Jubilant Life Sciences announced that one of its US subsidiaries Jubilant Cadista Pharmaceuticals has received approvals from the US Food and Drug Administration (US FDA) for four dosage formulations. These include escitalopram tablets olanzapine orally disintegrating tablet losartan potassium tablets USP, and hydrochlorothiazide tablets. Escitalopram is used for acute treatment of generalized anxiety disorder and acute and maintenance treatment of major depressive disorders.

Venus bags patent for Vancoplus

Chandigarh-based Venus Remedies, a leading research based global pharmaceutical company, has secured its first patent from Canada for its novel antibiotic adjuvant entity â€œVANCOPLUSâ€?. The patent has been granted by the Canadian patent office and is valid up to May 2027. The company is planning to launch the product in Canada in the next two years. Venus has already been marketing Vancoplus successfully in India and few of the merging markets across the globe.

As per a research report published by Canadian Antimicrobial Resistance Alliance (CARA), the community-acquired Methicillin-resistant Staphylococcus aureus (MRSA) cases have increased significantly from 19.5 percent in 2007 to 38.1 percent in 2010 and 40 percent of the cases have arisen from the community with increase in infection, among children and young adults.

US FDA OKs Agila's facility

Agila Specialties (Agila), injectables unit of Strides Arcolab Limited, announced that it has received US FDA approval for its Polish Sterile facility. This state-of-the-art facility located in Warsaw, Poland, manufactures vials, ampoules, pre-filled syringes and lyophilized injections.

With this approval all the eight global sterile injectable sites of Agila are now approved by the US FDA and EU authorities and places Agila amongst the largest global capacities for sterile injectables. Shipments from the Polish facility will commence within Q4 2012 and will run in full capacity by Q1 2013, as product transfers have already commenced. Venkat Iyer, CEO, Agila Specialties, said, â€œThis approval for our Polish sterile facility offers significant flexibility to our manufacturing which is currently experiencing strong demand on a worldwide basisâ€?.