Z THE **VEEDA** NEWSLETTER

FDA

• FDA Cites Florida Drugmaker for Serious Quality Violations

An FDA investigation into serous quality problems at a Florida pharmaceutical company revealed a litany of unsound practices in the manufacture of experimental drugs. <u>Read More</u>

• FDA Approves First Strattera Generic for ADHD, Plus Five Other First-Time Generics

The FDA approved the first generic versions of Strattera (atomoxetine) to treat attention-deficit hyperactivity disorder in pediatric and adult patients, including multiple strengths manufactured by Apotex, Teva, Aurobindo Pharma and Glenmark Pharmaceuticals. <u>Read More</u>

MERGER and ACQUISITION

• Strides Shasun announces joint venture with Vivimed labs.

Strides Shasun on Thursday informed that it has signed agreements with Vivimed labs to set up two joint venture companies. Both will be 50:50 joint venture companies. One of the companies in India will own the US FDA approved formulation facility in Alathur, Chennai, and the other company in Singapore will own certain approved ANDAs and product pipeline, as per BSE filing. <u>Read More</u>



• Pfizer Ltd enters into acquisition agreement with AstraZeneca.

Pharma major Pfizer Ltd has entered into acquisition agreement with AstraZeneca AB, Sweden pursuant to which the brand "Neksium" is being acquired by the company in India.The consideration amounted to Rs 75 crores, subject to completion of necessary conditions. <u>Read More</u>

FINANCIAL

• Novartis says generics sales will take Q2 hit, but it has a plan for the future.

You know the pricing pressure that burned the revenues of most generics makers in the first quarter? Well, Novartis executives say it is only getting worse, and that its Sandoz unit will succumb this quarter. Long term, the Swiss drugmaker said biosimilars will be the salve to heal the hurt, but for now the U.S. market will bring the pain. 'The impact of US pricing pressure and prior year launch timing is expected to have a higher impact on Q2 2017 sales growth than Q1,' the company said. <u>Read</u> <u>More</u>



• Lawsuit says Novo, OptumRx 'mutually benefited' from rebate scheme, while consumers paid the price

Novo Nordisk is the target, along with pharmacy benefit manager OptumRx, of a proposed class action lawsuit claiming a conspiracy to raise the price of diabetes medicines so that the drugmaker could pay rebates to the PBM, with U.S. consumers getting the sharp end of the stick in the deal <u>Read More</u>

CLINICAL TRIAL

• EMA Publishes Draft Guideline on Complying with Clinical Trial Master File Requirements

The European Medicines Agency says clinical trial master files should also include quality reports and checklists, product certifications and trial-specific computer system guides - essential documents that are not listed as required in ICH Good Clinical Practice guidelines. <u>Read More</u>

• EMA Revises Clinical Data Publication Guidance, Updates on Program -

The revision updates the previous version released in March, which clarified the agency's expectations for the data required to submit for publishing under the agency's clinical trial transparency rules. <u>Read More</u>

INDIA NEWS

• Granules India to raise funds worth Rs 500 crores through QIP

Granules India Limited, a leading pharmaceutical company has decided to give the approval to raise funds amounting to Rs 500 crores by an issue of equity shares through a Qualified Institutions Placements, subject to the approval of shareholders, as per BSE filing. <u>Read More</u>

• Natco launches Pomalid; first generic version of pomalidomide capsules in India.

NatcoPharma Limited on Wednesday, 10 May 2017, in its BSE filing said that it has launched a generic version of pomalidomide 1 mg, 2 mg, and 4 mg capsules in India. Pomalidomide is sold by Celgene Inc., in the USA, under the brand name POMALYST. <u>Read More</u>

VEEDA NEWS

• VEEDA CRO receives Best Clinical Research Organization - India award.

Veeda Clinical Research has been awarded as 'Best Clinical Research Organization - India' by Health & Safety Awards 2017 presented by Corporate Vision a leading business magazine and publication based in UK. <u>Read More</u>

• Veeda was selected for the industrial training of Drug inspectors by CDSCO.

The Central Drug Standards Control Organization (CDSCO)needs to keep itself abreast of the fastchanging scientific innovations, evolving international regulatory framework and other developments. <u>Read More</u>

EVENT AT VEEDA

• VEEDA CR Organized ICE GOLA PARTY for Employees.

As the summer is on its notch to give some relief from the scorching sun and work Veeda CR organized ICE GOLA party for its employees. Varieties of Ice Gola were enjoyed by all along with Interesting GAMES.



May Disease Focus

• Focus on Panic Disorder

Panic disorder (PD) is a common anxiety disorder that can adversely affect one's psychosocialhealth. PD is characterized by sudden episodes of fear, anxiety, or impending doom. <u>Read More</u>

Article Of The Month

veeda clinical research

• Quality, Not Price, is the Key Issue When Prescribing Generic Drugs in India

In the absence of a standard drug regulatory mechanism, Indian doctors rely on the reputation of companies who have demonstrated their commitment to quality over time. <u>Read More</u>

Upcoming Conferences and Events

Veeda Clinical Research will be participating in the CPHI CHINA Conference on June 20-22, 2017 Shanghai, China.

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