The Veeda Newsletter

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INDIAN PHARMA

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Japan drug makers begin contract manufacturing of generics in India.

Eisai is one of several Japanese pharmaceutical companies seeking to leverage their production capabilities in India to manufacture products for makers of generic drugs who are eager to cut their costs.The Japanese pharmaceutical giant is investing around 1 billion yen ($8.8 million) to install manufacturing equipment for active pharmaceutical ingredients and a trial line for drug formulations at its Vizag plant in Andhra Pradesh. It expects to be ready to offer its services to generic drug companies starting as early as 2020.

Read more at: https://asia.nikkei.com/Business/Trends/Japan-drugmakers-begin-contract-manufacturing-of-generics-in-India

US may widen probe to 18 major Indian pharma firms.

An official statement issued by Attorney General (AG) of Washington State, Bob Ferguson, said AGs of 45 other states have approached a federal court seeking to expand the pending complaint, increase the number of drug companies under probe to 18 from six and the number of affected drugs to 15 from two.

Read More: http://indianexpress.com/article/business/business-others/18-major-indian-pharma-companies-under-us-lens-for-price-fixing-drl-sun-glenmar-4919932/

US may widen probe to 18 major Indian pharma firms.

VTSIX Group, an India-based pharmaceutical company, will set up a factory in Cambodia in early 2018 after signing a land lease agreement with Phnom Penh Special Economic Zone (PPSEZ) on November 8.Hiroshi Uematsu, CEO of PPSEZ, said the upcoming pharmaceutical plant will comply with the Word Health Organisation's Good Manufacturing Practices (WHO GMP), adding that the entry of the Indian company into the local market will help diversify the country's industrial output.

Read More: http://www.khmertimeskh.com/92304/

Pharma sector raises demand of GST exemption on expired and damaged medicines

The pharma industry in the country has raised concerns demanding an exemption on expired and damaged medicines under the newly rolled out Goods and Services Tax (GST).Indian Pharmaceutical Alliance (IPA) in a statement said that the exemption of GST on expired and damaged stock of medicines is vital to prevent losses for the pharma industry.

Read More: http://knnindia.co.in/news/newsdetails/sectors/pharma-sector-raises-demand-of-gst-exemption-on-expired-and-damaged-medicines

REGULATORY NEWS

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CDSCO soon to begin inspections on drug testing labs to ensure compliance of D&C Rules

The Central Drugs Standard Control Organization (CDSCO) officials are in the process of devising an action plan to inspect drug testing labs for compliance to the Drugs and Cosmetics Rules. This is followed by recent Drug Controller General of India (DCGI)'s directive to the labs in the country to self audit for audit -readiness before a CDSCO inspection.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=105337&sid=1

FDA Expands Generic Drug Priority Reviews

Talk of bringing down the price of pharmaceuticals often hinges on generic competition, and the US is seeing approvals of new generic drugs faster and more consistently than ever – a trend likely to continue.The progress comes as US Food and Drug Administration (FDA) Commissioner Scott Gottlieb on Thursday indicated that the agency will expand which abbreviated new drug applications (ANDA) will see priority reviews.

Read More: http://www.raps.org/Regulatory-Focus/News/2017/11/09/28855/FDA-Expands-Generic-Drug-Priority-Reviews/

Drug regulator to make 'stability testing' a must for all medicines sold in India

India's drug regulator is set to propose amendments to the existing Drugs and Cosmetics Rules, 1945, to make "stability testing" mandatory for all drugs sold in the country before they are deemed suitable for use by patients."Stability testing will be made compulsory for all the drugs. An advisory letter has already been sent to the state drug controllers and a notification amending the rules is likely to come soon," said G.N. Singh, drug controller general of India (DCGI).

Read More: http://www.livemint.com/Industry/v68ljt3AJD9M0LmkbHgwEL/Drug-regulator-to-make-stability-testing-a-must-for-all-me.html

DCGI initiates measures to ensure smooth processing of applications for grant of manufacturing licenses

After making amendments in the Drugs and Cosmetics Rules to do away with renewal of licences for manufacture, sale and distribution of pharmaceutical products every five years, the Drug Controller General of India (DCGI) has initiated further measures to ensure smooth processing of applications for grant of manufacturing licenses.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=105840&sid=1

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CLINICAL RESEARCH

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Penn Medicine launches Northeast's first clinical trial for womb transplant

Penn Medicine will become the first hospital in the Northeast to conduct a clinical trial for uterine transplantation, an experimental procedure that could provide a new path to parenthood for women with uterine factor infertility. UFI, an irreversible form of female infertility, impacts about 50,000 women in the United States and 5 percent of women worldwide.

Read More: http://www.phillyvoice.com/penn-medicine-launches-northeasts-first-clinical-trial-womb-transplant/

Breast Cancer May Return Even 20 Years Later, Study Finds

Breast cancer can “smolder” and return even 20 years later unless patients keep taking drugs to suppress it, researchers reported Wednesday.They were looking for evidence that at least some breast cancer survivors might be able to skip the pills that reduce the risk of the breast tumors coming back, but found that even women with “low-risk” cancers had a small rate of recurrence 15 and 20 years later.

Read More: https://www.nbcnews.com/health/health-news/breast-cancer-may-return-even-20-years-later-study-finds-n819106

The rise of wearable technology for clinical trials

In recent years, there had been a surge surrounding the use of wearable technology for patient monitoring in clinical trials as they have the potential to impact trial costs and efficacy, and also their ability to process and analyze data streams.

Read More: https://pharmaphorum.com/partner-content/the-rise-of-wearable-technology-for-clinical-trials-insights-from-novartis/

Cancer drug starts clinical trials in human brain-cancer patients

A drug that spurs cancer cells to self-destruct has been cleared for use in a clinical trial of patients with anaplastic astrocytoma, a rare malignant brain tumor, and glioblastoma multiforme, an aggressive late-stage cancer of the brain. This phase Ib trial will determine if the experimental drug PAC-1 can be used safely in combination with a standard brain-cancer chemotherapy drug, temozolomide.

Read More: https://medicalxpress.com/news/2017-11-cancer-drug-clinical-trials-human.html

FINANCIAL NEWS

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Indiabulls Pharma receives Rs 155 crore investment from Clermont Group

Indiabulls Pharmaceuticals, a one year old pharma venture of Indiabulls GroupCompanies, on Monday announced that it has received Rs 155 Cr capital from Singapore based investment firm Clermont Group. Indiabulls Pharma said this new development will further boost an already rapidly growing business which the company has witnessed since its launch in May 2017.
Read
More: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indiabulls-pharma-receives-rs-155-crore-investment-from-clermont-group/articleshow/61919741.cms

Net profits of several top pharma cos decline by 40% in first half of 2017-18

Many of the top 30 Indian pharmaceutical companies reported sharp fall in their sales and profits during the first half of the year ended on September 2017 mainly on account of repeated US FDA actions, implementation of GST and price cuts. Adverse exchange fluctuations and competition in the overseas and domestic markets put additional burden on their working.With poor financial performances, pharmaceutical companies market capitalisation declined significantly and investors lost heavily.
Read More: http://pharmabiz.com/ArticleDetails.aspx?aid=105699&sid=1

Alembic Pharma Q2 net rises over 1 pc to Rs 121 crore

Alembic Pharmaceuticals today reported a 1.44 per cent increase in consolidated net profit at Rs 121.56 crore for the second quarter ended September 30, mainly on account of decline in total income.The company had posted a net profit of Rs 119.83 crore in the corresponding period of the previous fiscal. Read More: http://www.newindianexpress.com/pti-news/2017/nov/07/alembic-pharma-q2-net-rises-over-1-pc-to-rs-121-crore-1694317.html

Morepen inks pact with Vésale Pharma to boost presence in Rs 1000-crore probiotics market

Indian pharmaceutical firm Morepen Laboratories Ltd, listed on the Bombay Stock Exchange, has inked an exclusive agreement to market and distribute Belgian probiotics player Vesale Pharma International's major brands in the gastroenterology segment—a deal it hopes will help it strengthen its presence in India's growing probiotics market.
ReadMore: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/morepen-inks-pact-with-vsale-pharma-to-boost-presence-in-rs-1000-crore-probiotics-market/articleshow/61566578.cms

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MERGER & AQUISITION

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Cipla Health to expand consumer health biz with new launches and acquisitions

"We are looking at switching Cipla's prescription products into consumer products and organic launches wherever there is a huge unmet need of it like the immune-boosters that we launched now," said Anantha Nayak, Chief Executive Officer of Cipla Health. Read more: http://www.moneycontrol.com/news/business/companies/cipla-health-to-expand-consumer-health-biz-with-new-launches-and-acquisitions-2450317.html

Large merger and acquisitions back in Indian pharma

The Rs 3600 crore acquisition of Unichem's domestic business by Torrent Pharma has brought the mojo back into India pharma's merger and acquisition scene, which was eluding large deals in the past few years.Concerns related to the US market, which contributes major revenues for most of the leading firms, increasing regulatory concerns and price controls in the domestic market were forcing drug majors to be cautious in jumping into big deals. Read More: http://www.businesstoday.in/sectors/pharma/large-merger-and-acquisitions-back-in-indian-pharma/story/263399.html

ET Analysis: With Unichem Buy, Torrent's new M&A star in pharma

The Torrent-Unichem deal did not really surprise the pharma industry. The 73-year-old Mumbai-based UnichemBSE 0.13 % had been an attractive and an obvious target in the domestic formulations market for some years now, and Torrent buying it makes business sense.Besides, with the industry facing one of its challenging periods, consolidation is going to be the natural way to grow.

Read more at: http://economictimes.indiatimes.com/articleshow/61534856.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Teva looks to sell generics in China through joint venture with Guangzhou Pharma: Bloomberg

As the world's largest generics maker, Teva still doesn't have much of a presence in China, even though it is a country relies heavily on generics. The Israeli company is looking to remedy that by reportedly forming a joint venture with local company Guangzhou Pharma, according to Bloomberg.

Read More: http://www.fiercepharma.com/pharma-asia/teva-looks-to-sell-generics-china-through-guangzhou-pharma-joint-venture-bloomberg

VEEDA CRO NEWS

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GCP Training conducted at VEEDA CRO.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, and monitoring, auditing, recording, analyses and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial subjects.

The ICH-GCP is a harmonized standard that protects the rights, safety and welfare of human subjects, minimizes human exposure to investigational products, improves quality of data, speeds up marketing of new drugs and decreases the cost to sponsors and to the public. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected and consistent with the principles of the Declaration of Helsinki, and that the clinical trial data is credible.

Hence it's extremely necessary that each and every person involved in clinical research should understand these principles and oath to genuinely practice them in research purpose. Honesty, Integrity and Openness are amongst the values of Veeda and hence Veeda highly emphasizes on these trainings to be conducted and the values to be inculcated in each and every members of Veeda family.

Read More: https://www.veedacr.com/2017/flyers/Good%20Clinical%20Practice/Veeda-Good%20Clinical%20Practice.html

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ARTICLE OF THE MONTH

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Design considerations for handling dropouts in anti-depressant drug trials

In clinical trials, statistical analysis often requires certain assumptions about missing data for a valid statistical inference. If the dropout rate is high, a wrong assumption about the missing data may compromise the validity of statistical inferences.

Purpose

To mitigate the high dropout rates commonly observed in psychiatry clinical trials, we consider two design approaches for short-term controlled trials submitted in support of marketing applications for drug products for the major depressive disorder (MDD) indication: (1) shortening the trial duration and (2) treating time to treatment discontinuation as an alternative primary efficacy endpoint.

Methods

Subject-level efficacy data from 45 trials for drugs approved for an MDD indication between 1997 and 2014 were collected. We analyzed change from baseline in Hamilton Depression Rating Scale (HAMD-17) total score using the mixed model repeated measures approach.

Source : https://www.sciencedirect.com/science/article/pii/S1551714417305347

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