

The Veeda Newsletter





DCGI directs drug testing labs across country to do self audit before CDSCO inspections



Biosimilars in oncology: a €2billion opportunity for European healthcare



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Robots could help detect cancer in less than a second, trials suggest





INDIAN PHARMA

Industry protests at new drug and devices price controls in India

The Indian government is on the war path again. The Department of Pharmaceuticals is looking to change the method of approving prices of new drugs, despite a clear division in its ranks about amending the drug price control order, in a move that would bring non-essential drugs under price control, reports The Pharma Letter's India correspondent.

Read More: https://www.thepharmaletter.com/article/industry-protests-at-new-drug-and-devices-price-controls-in-india

Chemists raise concerns over 'confusing' GST norms about expired medicines

Chemists in Pune and across the country are facing several issues while implementing the Goods and Services Tax (GST), especially during transactions pertaining to expired and recalled products. They have written to GST Commissioner Upender Gupta, raising concerns about how certain GST norms contradict some of the regulations under different Acts that govern medicine trade.

Read More: http://indianexpress.com/article/india/chemists-raise-concerns-over-confusing-gst-norms-about-expired-medicines-4910006/

Govt moves to finalize methodology to fix prices of new drugs

The government has initiated the process to finalize a new methodology to fix the prices of new drugs amid concern over delays in approving prices, a prerequisite for launching a new drug. The government is considering doing away with the present practice of deciding a new price for each applicant of "new drug", according to people in the government who are privy to the development.



Read More:

http://www.livemint.com/Industry/RddH0wXp6Q4s H1E3qaPsyK/Govt-moves-to-finalize-methodology-to-fix-prices-of-new-drug.html

India is second largest market for pharma, biotech workforce: report

With 13.7 per cent contribution to the global pharmaceuticals and biotechnology workforce, India has emerged as the second largest market for the industry, a report by professional networking giant LinkedIn has revealed.

Read More: http://www.navhindtimes.in/india-is-second-largest-market-for-pharma-biotech-workforce-report/





REGULATORY NEWS



DCGI directs drug testing labs across country to do self audit before CDSCO inspections

To effectively assess the status of compliance across drug testing labs in the country as per global regulatory requirements. Drug Controller General of India (DCGI) has asked the drug testing labs to verify and assess their compliance levels through a self- audit to ensure audit -readiness before Central Drugs Standard Control Organization (CDSCO) inspection teams assess good laboratory practices.

The inspections which will be conducted jointly by CDSCO officials and respective state drug controllers. The joint inspection testing labs is planned after a gap of 13 years.

Read More: http://www.pharmabiz.com/NewsDetails.aspx? aid=104710&sid=1



The FDA Has Approved a Faster Way to Check for Allergies

Medical diagnosis is a field that doesn't want to be left behind as more technology takes over health care — and rightly so. Arriving at a correct diagnosis faster can spell the difference between a life lost and a life saved. To wit, a novel method has just been approved by the U.S Food and Drug Administration (FDA) that allows faster allergy diagnosis using just a single drop of blood.

Read More: https://futurism.com/the-fda-has-approved-a-faster-way-to-check-for-allergies/

The US is approving more generic drugs than ever

This record push is part of an effort to lower prescription drug costs. Generic drugs, which work the same way as previously patented pharmaceuticals, are less expensive than name-brand drugs. And although the FDA has no control of how much pharmaceutical companies can charge for their drugs, more generic drugs on the market theoretically drives market prices down by adding in more competition.

Read More: https://qz.com/1101897/more-generic-drugs-were-approved-by-the-us-fda-in-fy-2017-than-ever-before/

FDA Panel Considers Gene Therapy for Blindness

A girl saw her mother's face for the first time. A boy tore through the aisles of Target, marveling at toys he never knew existed. A teen walked onto a stage and watched the stunned expressions of celebrity judges as he wowed "America's Got Talent."

Caroline, Cole, Christian. All had mere glimmers of vision and were destined to lose even that because of an inherited eye disease with no treatment or cure.

Until now.

Read More: https://www.usnews.com/news/best-states/pennsylvania/articles/2017-10-09/seeing-hope-fdapanel-considers-gene-therapy-for-blindness





CLINICAL RESEARCH



Clinical trials offer hope for treating dementia

Sinclair Conference Center, the Miami Valley chapter of the Alzheimer's Association will be hosting a community dinner. Program highlights include a review of the joys of music therapy for people with dementia. As well, the presenters will share information on current Alzheimer's treatments.

Read More:

http://www.mydaytondailynews.com/news/local/clinical-trials-offer-hope-for-treating-dementia/M2PTANlwBCu9H2yeNOt2LN/



Robots could help detect cancer in less than a second, trials suggest

Trials found that computer programmes were able to distinguish potentially dangerous tumours from harmless growths with high levels of accuracy. The research involved bowel cancer - the fourth most common form of the disease in the UK, with more than 40,000 diagnoses annually. In a trial, the AI system was able to distinguish tumours from endoscopy images with 94 per cent accuracy.

Read More: http://www.telegraph.co.uk/news/2017/10/29/robots-could-help-detect-cancer-less-second-trials-suggest/

Measuring The Impact Of Reforms On India's Clinical Trial Environment

From then on, the view of India as a destination for low-cost Phase II to III trials with a large treatment-naive patient pool changed. Looking into the trial numbers after these changes, a sharp decline in industry-sponsored trials were observed between 2013 and 2015. Figure 1below shows the trials registered in India between 2013 and 2016. Overall there was a reduction in Phase I to IV trials by 30 to 35 percent.

Read More https://www.clinicalleader.com/doc/measuring-the-impact-of-reforms-on-india-s-clinical-trial-environment-0001

How To Conduct More Efficient Clinical Trials Using Registries

Integrating clinical trials within registries offers several opportunities: avoiding duplicative data collection, identifying and recruiting patients more efficiently, and accelerating decision making, to name a few. These efficiencies have the potential to reduce clinical trial costs — especially when a registry is used to conduct multiple clinical trials.

Read More: https://www.clinicalleader.com/doc/how-to-conduct-more-efficient-clinical-trials-using-registries-0001





FINANCIAL NEWS

Biosimilars in oncology: a €2billion opportunity for European healthcare

QuintilesIMS' Murray Aitken examines the potential for savings from a new wave of oncology biosimilars – but says payers have to invest in education and incentives to maximise uptake. The global pharmaceutical industry is in the midst of an exciting period of innovation, with new treatments for rare diseases, cancer drugs and cutting-edge cell and gene therapies reaching the market and improving patient outcomes.

Read More: https://pharmaphorum.com/views-and-analysis/biosimilars-oncology-european-healthcare/

Cost cuts are coming for Allergan, CEO says. But a breakup isn't

Heading into Allergan's third-quarter conference call, executives knew investors were skittish about the prospect of Restasis generics. So they spelled out their solution loud and clear: Cost cuts are coming, and "rapidly."

Read More: http://www.fiercepharma.com/financials/cost-cuts-are-coming-for-allergan-ceo-says-but-a-breakup-isn-t

Cost cuts are coming for Allergan, CEO says. But a breakup isn't

Heading into Allergan's third-quarter conference call, executives knew investors were skittish about the prospect of Restasis generics. So they spelled out their solution loud and clear: Cost cuts are coming, and "rapidly." Executives are currently sifting through the details of cost-squeezing proposals they drew up earlier this year, CEO Brent Saunders said on the call.

Read More:

http://www.fiercepharma.com/financials/cost-cuts-are-coming-for-allergan-ceo-says-but-a-breakup-isn-t



Bayer's pharma, consumer sales suffer in Q3 as it works to close Monsanto deal

Some analysts and market watchers worried about Bayer's focus when the drugmaker went after agrochem giant Monsanto in a \$66 billion deal last year, and now the company's third-quarter results have confirmed those fears.

The company's pharma results were "messy," according to a Thursday note from Bernstein analyst Jeremy Redenius. The drugmaker reported €8 billion in sales for the group, missing consensus estimates by 6%.

Read More: http://www.fiercepharma.com/financials/bayer-s-pharma-consumer-sales-lag-q3-as-it-works-to-close-monsanto-deal





MERGER & AQUISITION

Torrent Pharma in advanced talks to buy Unichem's India business for Rs3,200-3,300 crore

Torrent Pharmaceuticals Ltd is likely in advanced discussions to acquire the domestic formulations business of Unichem Laboratories Ltd for Rs3,200-3,300 crore, two people aware of the development said on the condition of anonymity.



http://www.medicalbuyer.co.in/index.php/daily-news/14874-torrent-pharma-in-advanced-talks-to-buy-unichem-s-india-business-for-rs-3200-3300-crore



China's Fosun Pharma to buy French drug distributor Tridem in overseas expansion push

Through the acquisition of Tridem, which has a presence in 21 French-speaking African countries and regions, Fosun Pharma could tap into the promising continent with the help of Tridem's "mature sales network and upstream and downstream resources", the company said in a filing to the Hong Kong stock exchange on Sunday. A subsidiary of China's Fosun Group, which is led by billionaire Guo Guangchang, Fosun Pharma has in recent years been accelerating its push into overseas markets, including Europe, Africa, the US and India.

Read More: http://www.scmp.com/business/china-business/article/2117613/chinas-fosun-pharma-buy-french-drug-distributor-tridem

China's maiden billion-dollar takeover of an Indian pharma giant

Creating a new chapter in the history of China and Indian pharmaceutical industry, China's drug giant Fosun Pharma has acquired approximately 74 per cent in India's Gland Pharma at a valuation for \$1.09 billion. In the regulatory filing, Fosun Pharma and Fosun International said following the completion of the acquisition, Gland Pharma has become an indirect non-wholly owned subsidiary of Fosun Pharma and Fosun International.

Read More: https://www.biospectrumasia.com/analysis/25/9663/chinas-maiden-billion-dollar-takeover-of-an-indian-pharma-giant-.html

Sun Pharma's Ranbaxy acquisition continue to hamper growth

Sun Pharmaceutical Industries Ltd, a Rs.30,000 crore plus company is passing through a difficult phase especially during last few quarters due to warning letters from US FDA, fewer launches and competition. It suffered heavy setback during the first quarter ended June 2017 incurring a net loss of Rs.323 crore before non-controlling interest as against net profit of Rs.2,268 crore. Its consolidated net sales also declined by 23 per cent to Rs.6,167 crore from Rs.8,007 crore. With net loss, its EPS worked out to negative Rs 1.8 as compared to Rs.8.5 in the last year.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=104953&sid=1





Nov-Disease Focus

Headaches: Focus on Migraines

Migraine disorder is considered the most disabling and burdensome of all the headache disorders. Migraine headaches affect over 28 million Americans. It is disabling and burdensome to individuals and their families. It also has a negative impact on society primarily due to high economic costs and lost productivity. The prevalence of migraine disorder is approximately 18.2% in females, and 6.5% in males. The median frequency is 1.5 attacks per month, with 10% of migraine sufferers experiencing weekly attacks. The median attack duration is about 24 hours, but episodes may last as long as 2-3 days in 20% of patients. The annual indirect costs associated with missed workdays and reduced productivity due to migraines is estimated at over \$13 billion.



A migraine attack is an episodic headache lasting between 4 and 72 hours when untreated. The pain is frequently unilateral or throbbing, and of moderate or severe intensity. Migraine attacks are usually associated with nausea, vomiting, or sensitivity to light, sound, or movement. Each patient who experiences a migraine attack will have some combination of these characteristics, but not all features are present in every migraine attack. A minority of migraine attacks are preceded or accompanied by an aura. An aura consists of transient and focal neurologic symptoms. The symptoms may be visual, sensory, or motor phenomenon and may involve language or brain stem disturbances. It is important to correctly differentiate migraine from other types of headache before determining the optimal treatment. Cluster headache is the most painful of the primary headaches. It comes on without warning, is unilateral, and is characterized by a rapid increase in pain intensity. Cluster headaches lasts 45-90 minutes on average, compared with 4-72 hours for migraine, and unlike migraine, is not usually associated with aura, nausea, and vomiting. In contrast to migraine, cluster headache is four times more common in men. Tension headache and analgesic overuse headache are rarely accompanied by nausea, vomiting, photophobia, and phonophobia. These are often frontal, bilateral headaches, accompanied by tightness around the neck and shoulder muscles.

Read More: https://www.pharmacychoice.com/education/diseases/migraine.cfm? disease=migraine





ARTICLE OF THE MONTH

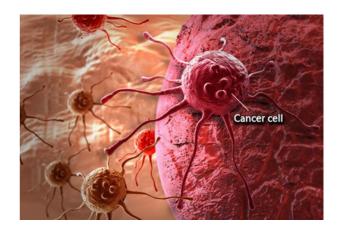


New weapons to fight cancer: Artificial intelligence and cryptography therapy

A population of stem cells that gives rise to blood cells are made in the bone marrow; they constantly divide and multiply.

Stem cells have finite number of divisions and such sort of genetic constants is called "Hayflick timing mechanism" or "Hayflick clocks".

Hayflick's limit equates to 53 divisions and pure mathematically it represents calibration invariant.



Some new cells remain as stem cells with Hayflick memory and other develop into mature blood cells before being released into the bloodstream.

As is known, the parent stem cells with Hayflick memory are usually called a pluripotent stem cells which are developing into either a lymphoid or myeloid cells. It give rise to the different lineages.

Read More: https://www.pharma-iq.com/pre-clinical-discovery-and-development/articles/new-weapons-to-fight-cancer-artificial

