The Veeda Newsletter

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Frost & Sullivan awarded Veeda CRO as India Clinical Research Company of the Year Award 2017.

MEET US AT CPHI WORLDWIDE.

Indian pharma market clocks growth of 2.8% to Rs.10,420 crore in September 2017

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

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INDIAN PHARMA

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Indian pharma market clocks growth of 2.8% to Rs.10,420 crore in September 2017

Indian Pharmaceutical Market (IPM) has registered a growth of only 2.8 per cent during September 2017 to Rs.10, 420 crore and 3.7 per cent during the first half ended April-September 2017. According to AIOCD Pharmasofttech AWACS Pvt Ltd report, the half yearly growth has been affected due to GST run up and implementation. The volumes of established product have shown a turnaround in this month. However, price component will continue to pull the market down.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=104800&sid=1

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/

Indian drugmakers' revenue growth in US may cool off to 7-10% over 3 years: ICRA

Indian drug makers' revenue growth in US may cool off to 7-10 percent over the next three years after mid- to high double-digit growth over the last five years owing to rising competition, fewer blockbuster drugs going off-patent, generic adoption reaching saturation levels and regulatory overhang, according to rating firm ICRA.

Read More:
http://www.moneycontrol.com/news/business/companies/indian-drugmakers-revenue-growth-in-us-may-cool-off-to-7-10-over-3-years-icra-2403575.html

Indian pharma can no longer ignore digital wave – EY report

The pharmaceutical industry is currently in a 'perfect storm' given pricing pressures and demands not just from the domestic market but also on the global front as well as supply side pressures. Domestic markets continue to remain a key focus area for the Indian pharmaceutical companies. To fully realise the potential of the market, the sector can no longer ignore the digital wave characterized by increasingly informed patients and physicians, new range of customers and new disruptive market entrants, according to Sriram Shrinivasan, Global Life Sciences Emerging Markets & Generics Leader, EY.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=104496&sid=2

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REGULATORY NEWS

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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 a Central Drugs Standard Control Organization (CDSCO) inspection team 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

Regulatory Changes Position China as a Global Clinical Trial Destination.

Global biopharma companies have long held concerns over China's slow drug and medical device approval Philip Gregory system, with long processing times and rigid intellectual property (IP) restrictions delaying market launch and uptake. Throughout this year, the China Food and Drug Administration (CFDA) has been addressing these issues to adjust evaluation and approval procedures, in an effort to attract advanced foreign drugs to China.

Read More: http://www.appliedclinicaltrialsonline.com/regulatory-changes-position-china-global-clinical-trial-destination

CDSCO streamlines ICEGATE system for online tracking of drugs at ports

In order to ensure that drugs imported at ports are tracked in a proper manner, the Central Drugs Standard Control Organization (CDSCO) has streamlined ICEGATE system to overcome procedural flaws which had of late led to its poor implementation impacting the trade and industry badly. ICEGATE that stands for the Indian Customs Electronic Commerce Interchange Gateway is a portal providi

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=104192&sid=1

DCGI plans surprise tests in labs to check drug quality

"Surprise inspections" of all accredited laboratories is in the offing, according to a senior official in the drug controller's office. "All private drugs and cosmetics testing facilities in India will have to undergo auditing, addressing all elements of quality by the government," said the official cited above, requesting anonymity. Although every drug manufacturer has in-house testing facilities, the public drug testing laboratories approved under Drugs and Cosmetics Rules cater to the testing requirements of manufacturing units that lack specialized facilities.

Read More: http://www.livemint.com/Industry/wd3INVcJwMx4X16M8gY3mJ/DCGI-plans-surprise-tests-in-labs-to-check-drug-quality.html

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CLINICAL RESEARCH

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To market new drugs in India, global trials must include Indians

In a move to ensure efficacy of medicines sold in India, the drug regulator has made it mandatory for companies to include Indian patients in global clinical trials if they want to market in India a new drug developed outside the country.The decision was taken in a recent technical committee meeting, headed by director general of health services Jagdish Prasad. The committee, which was formed following directions from the Supreme Court, has a mandate to supervise clinical trials on new chemical entities.

Read More: https://timesofindia.indiatimes.com/india/to-market-new-drugs-in-india-global-trials-must-include-indians/articleshow/61029119.cms

Cancer Cure News 2017: FDA Approves of New Cancer

Treatment Involving White Blood Cells

According to BBC News, the United States government has now approved of the CAR-T treatment, which uses a cancer patient's own immune system to destroy cancer cells. The U.S. Food and Drug Administration has given the go signal for the revolutionary form of cancer treatment, saying that it was a "historic" decision.

Read More: http://www.christianpost.com/news/cancer-cure-news-2017-fda-approves-of-new-cancer-treatment-involving-white-blood-cells-199078/

Russian, Indian firms ink deal to produce drugs for HIV

Russian state-run National Immunobiological Company (Nacimbio) on Tuesday announced signing an agreement with Indian pharma firm Mylan Laboratories on the transfer of technology for producing readymade dosage forms and active pharmaceutical agents for the treatment of HIV.

Read More: https://www.canindia.com/russian-indian-firms-ink-deal-to-produce-drugs-for-hiv/

The Crisis in Gynecological Cancer Research

As an ovarian cancer patient whose life is being extended by a clinical trial, I was delighted to learn this summer that research on gynecological cancers is undergoing an unusually productive period. But I'm dismayed that at the same time there has been a steep decline in clinical trials available in the field.

Read More: https://www.nytimes.com/2017/09/14/well/live/the-crisis-in-gynecological-cancer-research.html

FINANCIAL NEWS

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Intas Pharmaceuticals to go for $4-billion deals in a month

Ahmedabad-based Intas Pharmaceuticals had emerged as the dark horse last October when it acquired the generic business of Actavis in the UK and Ireland for Rs 5,100 crore ($732 million) from Teva. Intas beat global giants Mylan and Novartis, besides domestic rival Aurobindo Pharma, to the deal. In less than a year, Intas will be bidding for three assets worth $4 billion by mid-October.

Read More: http://www.business-standard.com/article/companies/intas-pharma-to-bid-for-4-bn-deals-in-a-month-117091401581_1.html

Bemoaning Budget Cuts, Health Care Navigators Say Feds Don't Get It.

The Trump administration says many of the organizations that help people enroll in health plans on the federal insurance marketplaces don't provide enough bang for the buck, sometimes costing thousands of dollars to sign up each customer. So it is cutting their funding, some by as much as 90 percent, the government told the groups last week.

Read More: http://www.npr.org/sections/health-shots/2017/09/20/552094974/bemoaning-budget-cuts-health-care-navigators-say-feds-dont-get-it

Teva finishes women's health sale with deals worth $1.38B

Teva, which has been rumored to be looking to offload its women's health unit since April, has finally gotten that done. After selling one piece of the biz for more than $1 billion a week ago, the beleaguered drugmaker today unveiled terms to sell the remaining products for $1.38 billion, which it can use to pay down debt.

Teva announced a sale of contraception, fertility, menopause and osteoporosis products to CVC Capital Partners Fund VI for $703 million Monday morning. The products generated $258 million in sales last year.

Read More: http://www.fiercepharma.com/m-a/teva-finishes-women-s-health-sale-deals-worth-1-38b

How Kite came from a position of strength to get Gilead to boost its buyout price by 42%

Usually when two biopharma companies negotiate a merger and the final price ends up soaring way past the original offering price, it's because there's another bidder lurking in the wings, ready to swoop in with a better offer. But Gilead Sciences' $12 billion buyout of Kite Pharma wasn't your everyday big bio deal—far from it, in fact.

Read More: http://www.fiercepharma.com/m-a/how-kite-came-from-a-position-strength-to-boost-its-buyout-price-by-42

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MERGER & AQUISITION

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Allergan Signs Deal With Indian Tribe to Protect Patents.

Seeking to shield its blockbuster eye drug Restasis against a second round of patent attacks, Allergan has transferred several Restasis patents to the Saint Regis Mohawk Tribe. The unusual move drew responses ranging from “innovative” to “sleazy,” according to an article by FiercePharma.

Read More:
https://www.managedcaremag.com/news/allergan-signs-deal-indian-tribe-protect-patents

Landmark M&A Deals Continue to Shape Big Pharma

Merger and acquisition activity has played a massive role in the formation of the pharmaceutical industry as it exists today. Historic deals, like Pfizer's 2009 purchase of pharmaceutical giant Wyeth for $68 billion and Glaxo Wellcome's purchase of SmithKline Beecham for $76 billion in 2000, have created a consolidated market that's often driven forward by the innovations of smaller companies. Lexaria Bioscience Corp. (CSE: LXX) (OTC: LXRP) (LXRP Profile),

Read More: http://www.prnewswire.co.uk/news-releases/landmark-ma-deals-continue-to-shape-big-pharma-642860913.html

Pharma strategy: GlaxoSmithKline sets up first team for acquisitions in 93 years

GlaxoSmithKline (GSK) Pharmaceuticals is scouting for acquisitions in the domestic market for the first time since it started its operations in the country 93 years ago, according to a Business Standard (BS) report on Monday. The change in strategy for a company which has preferred to rely on its traditional strengths in the branded generics space. The decision to grow inorganically comes at a time when the government is increasing price over branded a generic medicine which has affected the company's profitability.

Read more at: http://www.ibtimes.co.in/pharma-strategy-glaxosmithkline-sets-first-team-acquisitions-93-years-740835

Lupin's US arm takes over Symbiomix Therapeutics

LupinBSE 0.15 % on Wednesday said it has acquired Symbiomix Therapeutics, a US-based company specialising in drugs for gynaecologic infections, for cash considerations of $150 million, or about Rs 980 crore. The acquisition, made through the firm’s US subsidiary Lupin Pharmaceuticals, involves upfront payment of $50 million, other time-based payments, and sales-based contingent payments. Lupin said the acquisition is funded from internal funds.

Read more at: http://economictimes.indiatimes.com/articleshow/61033246.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

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World HRD CONGRESS honored VEEDA CLINICAL RESEARCH by Mark OF Excellence Award 2017.

Veeda Clinical Research was honored by MARK OF EXCELLENCE award for its excellence in providing continuous quality services in India.
Gujarat Best Employer Brand awards 2017 were announced by World HRD Congress in association with STARS Group, where in many companies from Gujarat has been recognized and awarded for their contribution.
Read more at: https://www.veedacr.com/2017/Newsletter/Oct2017/World%20HRD%20CONGRESS%20honored%20mark%20Of%20Excellence%20Award%202017%20-%20Copy.html

Mr. Nirmal Bhatia, CFO & Mr. Venu Madhav, COO,VEEDA CLINICAL RESEARCH MARK OF EXCELLENCE AWARD 2017.

United States Food and Drug Administration (USFDA) - BioResearch Monitoring Program (BIMO) conducted 2 Inspections at Veeda CR – Ahmedabad

Veeda CR is glad to share the successful completion of 2 USFDA Inspections at 2 of its locations at Ahmedabad in Sep-2017. Both the Inspections were Routine Inspections by BIMO (BioResearch Monitoring Program - USFDA) covering Clinical Phase of Healthy Volunteer BE studies.
The outcome of both the Inspections was - no issues identified in the studies conducted at Veeda facilities, i.e. No 483.
Read More: http://www.veedacr.com/2017/flyers/USFDA%20-%20BioResearch%20Monitoring%20Program/USFDA%20%E2%80%93%20BioResearch%20Monitoring%20Program.html

VEEDA CRO Receives Frost & Sullivan's India Clinical Research Company of the Year Award 2017.

Frost & Sullivan bestows 2017 Indian Clinical Research Company of the Year Award to Veeda Clinical Research Pvt. Ltd. for strong performance in terms of growth, service portfolio & Key initiatives in the field of clinical research. The award was received by Mr. Apurva Shah & Mr. Binoy Gardi, GMD & Founder, VEEDA CLINICAL RESEARH in presence of distinguished business and industry leaders in a glittering function held on 05 Oct 2017 at ITC Maratha, Mumbai.
Read More: https://www.veedacr.com/2017/Newsletter/Oct2017/VEEDA%20CRO%20Receives%20Frost%20&%20Sullivan's.html

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OCT- Diesease Focus

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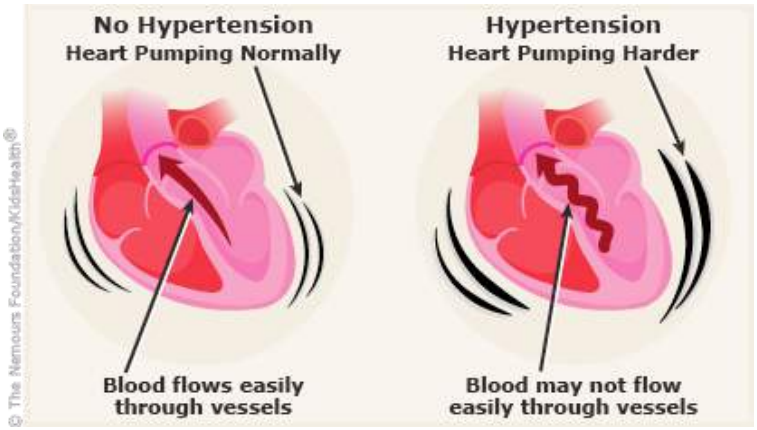
Hypertension Patients – the Pharmacist as Patient Risk Manager.

Today's pharmacist has several profession roles, many of which have evolved in just the last generation of pharmacists. In Kampe v Stark the Missouri appellate court held, "By properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty to appellant."1That was in1992 when in large parts of the country a pharmacist's only job was to lick, stick, count, and pour. Only six year later Kampe was overruled in the case of Horner v. Spalitto2, which held, a pharmacist's "education and expertise will require that he or she do more to help protect their patrons from risks which pharmacists can reasonably foresee."

To Monitor, To Warn

The Horner case held a pharmacist may have an additional duty to warn and to monitor.2 A duty to warn and monitor is a significantly higher professional, if not legal, duty. It is a duty which pharmacists are increasingly embracing. To warn and to monitor defines a role in which pharmacists are becoming their patient's risk manager. It is prospective drug review and communication, which includes written and oral counseling. Increasingly pharmacists are protecting patients and saving lives.



Hypertension is a good example of the impact today's pharmacists can have on health and quality of life. There are an estimated 65 million people in the United States with hypertension3 of which 42 million are uncontrolled.4 Some of these are undiagnosed, but many are patients on medication filled in pharmacies every day. One of the places pharmacists can have the greatest impact lies in the fact "that approximately 50% of individuals discontinue antihypertensive medications within 6 to 12 months of their initiation."4

Read More: http://www.pharmacychoice.com/education/diseases/hypertension.cfm?disease=hypertension

Three survival tips when facing the patent cliff

When drugs reach their patent expirations, generic manufacturers typically enter the market with products mostly far cheaper than the original. This is the so-called “patent cliff”.

This places pharma companies in a difficult position due to huge expenditures on R&D, possibly irretrievable costs, and the potential to lose up to 90 per cent of their sales.

However, companies can adopt methods to maximize the time to commercialize a drug within the patent protection period and execute life cycle management strategies that enable business sustainability for a drug well beyond its patent cliff.

The need to obtain a significant return on investment within the patent protection period

The Food and Drug Administration (FDA) normally grants a patent for 20 years. While this may seem like a long period in which to gain a significant return on investment (ROI), it is important to remember that it can take from eight to 12 years to gain FDA approval.

One example of this lengthy process is that, according to US Federal Law, an approved marketing application must be obtained before a drug can even be trialled or distributed across state lines.

This means that clinical trials in other states, especially orphan drugs for rare diseases where it is hard to find sufficient participants, require an exemption.

Foreseeing the paper storm

For the launch process to be successful, strategizing for market access needs to begin when a pharma company plans its first set of trials.

Read More: https://www.pharma-iq.com/market-access/articles/three-survival-tips-when-facing-the-patent-cliff

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UPCOMING EVENT & CONFERENCE:

1. **CPHI WORLDWIDE.**
   Oct 24 – 26, 2017,
   Messe Frankfurt, Germany.

   For Meeting Appointment Contact:
   Mr. Rajkumar Agarwal.
   Rajkumar.Agarwal@veedacr.com
   OR info@veedacr.com.

2. **14TH PHARMACOVIGILANCE 2017**
   Nov 9, 2017.
   Mumbai, India.

   For Meeting Appointment Contact:
   Dr. Pranjal Bordoloi.
   info@veedacr.com.

3. **CPHI INDIA.**
   Nov 28 - 30,2017.
   Mumbai, India.

   For Meeting Appointment Contact:
   Mr. Abhishek Patel.
   Abhishek.patel@veedacr.com,

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