The Veeda Newsletter

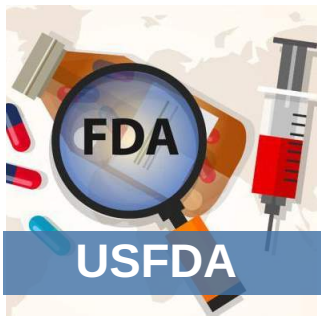
SEP 2017
ISSUE 9

INDIAN PHARMA NEWS

The State of Pharmaceutical Industry in India – An Overview.

Where's the relief from drug pricing fury?

MEET US AT CPHI WORLDWIDE.



USFDA hikes fee for processing ANDA by $1 lakh for FY18.

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INDIAN PHARMA

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The State of Pharmaceutical Industry in India – An Overview

"Currently the industry is growing at a rate of 9-10% year-on-year, which is a healthy growth because this is largely a volume led business. This is a fundamental advantage of an emerging market economy like India; given the large base, double digit growth numbers are not observed in developed countries like United States," said Kedar Upadhye, Global Chief Financial Officer, Cipla Ltd.

Read More: http://health.economictimes.indiatimes.com/news/pharma/the-state-of-pharmaceutical-industry-in-india-an-overview/60273583

New Draft Pharma Policy Shows Interest in Price Regulation, but Also in Crimping Price Regulator

An 18 page draft pharmaceutical policy by the department of pharmaceuticals (DOP) was circulated last week to various organizations working in the pharmaceutical industry as well as civil society. The draft shows that the government is keen to focus on the quality of Indian drugs, reducing the time taken for drug approval, increasing indigenous discovery of drug molecules and reducing dependence on China for raw materials.

Read More: https://thewire.in/169369/new-draft-pharma-policy/

Draft Pharmaceutical Policy 2017: 'Recognizing drug quality concerns in India signals paradigm shift'

A common feature in the Government of India's (GoI's) response to any allegation of sub-standard medicines supplied by the Indian industry is to deflect attention by insinuating a "foreign-hand" that foreign governments and their industry conspire to defame the Indian industry because they cannot compete with the Indian pharmaceutical industry.

Read More: http://indianexpress.com/article/india/draft-pharmaceutical-policy-2017-recognising-drug-quality-concerns-in-india-signals-paradigm-shift/

India's proposed pharma marketing rules hit legal roadblock

The country's law ministry has rejected draft marketing rules, which were prepared by the Department of Pharmaceuticals (DoP) after nearly two years of deliberations, saying they cannot be passed under the proposed legal framework, industry sources told Reuters.

Read More: http://health.economictimes.indiatimes.com/news/pharma/indias-proposed-pharma-marketing-rules-hit-legal-roadblock/60200521

Govt plans bulk drugs parks, import curbs to boost manufacturing in India

In the draft pharmaceutical policy framed by the department of pharmaceuticals under the ministry of chemicals and fertilizers, the centre has proposed "peak customs duty" for all APIs that can be indigenously manufactured.

Read More: http://www.livemint.com/Industry/qGhXkzNYDoP1ueP65OtZyH/Govt-plans-bulk-drugs-manufacturing-plants-import-curbs-to.html

USFDA NEWS

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USFDA hikes fee for processing ANDA by $1 lakh for FY18.
The hike was made under Generic Drug User Fee Amendments of 2017 (GDUFA II). The fee in FY17 was USD 70,480.According to a notification on USFDA's website, fee for Drug Master File was reduced to USD 47,829 for 2017-18 from USD 51,140 in the last fiscal. **Read More:** http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/usfda-hikes-fee-for-processing-anda-by-1-lakh-for-fy18/articleshow/60276221.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

FDA Approves Rabies IgG. Available in Early 2018.
Rabies is a life-threatening condition that impacts approximately 40,000 Americans each year. In the U.S., most human cases are the result of being bitten by an infected wild animal, especially raccoons, skunks, and bats. In other parts of the world, being bitten by a rabid dog accounts for many cases.
Read More: http://www.raredr.com/news/fda-approves-rabies-igg

US FDA plans facility inspection efficiency drive.
The US Food and Drug Administration (FDA) has released a document to address the integration of pharmaceutical facility evaluations and inspections.
Read More: http://www.in-pharmatechnologist.com/Regulatory-Safety/US-FDA-plans-facility-inspection-efficiency-drive

FDA puts new restrictions on hiring of foreign scientists, documents show .
he FDA recently began directing hiring managers not to extend any employment offers — including for fellowship and contractor positions — to any individual who has not lived in the U.S. for at least three of the five previous years, according to briefing materials shared with STAT that have been presented to some agency employees.
Read More: https://www.statnews.com/2017/08/11/fda-hiring-non-citizens/

CDSCO all set to launch portal to regulate online pharmacy trade.
“Based on the recommendations and agreement with all the concerned stakeholders, the Union health ministry is currently on the final phase to frame a policy on the use of information technology in online pharmacy. This will be taken forward without disturbing existing systems followed by a clear-cut policy on regulating online pharmacies,” says Drug Controller General of India (DCGI) Dr G N Singh.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=103445&sid=1

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CLINICAL RESEARCH

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CRO services industry forecast to 2022 scrutinized in new research

The CRO Services industry development trends and marketing channels are also analyzed and the feasibility of new investment projects are assessed and overall research conclusions offered. With the tables and figures the report provides key statistics on the state of the industry and is a valuable source of guidance and direction for companies and individuals.

Read More: https://www.whatech.com/market-research/it/366906-cro-services-industry-forecast-to-2022-scrutinized-in-new-research

Basic studies of how our brains work are now clinical trials, NIH says

Although NIH revised its definition of clinical trials in 2014, the agency is only now implementing it as part of a new clinical trials policy. Concerns arose this summer when an NIH official said the definition could apply to many basic behavioral research projects, including brain studies—for example, having healthy volunteers perform a computer task while wearing an electrode cap or lying in an MRI machine.

Read More: http://www.sciencemag.org/news/2017/08/basic-studies-how-our-brains-work-are-now-clinical-trials-nih-says

Discovery's 'First In Human' Calls Much-Needed Attention To Clinical Trials

The series comes at a time when clinical trial participants are in short supply, particularly in cancer—the disease that afflicts two of the four patients who are the stars of the documentary. Only about 3% of cancer patients choose to enroll in clinical trials. This is a problem, particularly now, when innovation in oncology is at an all-time high, leaving pharmaceutical companies and academic researchers desperate for patients to participate in their research.

Read More: https://www.forbes.com/sites/arleneweintraub/2017/08/17/discoverys-first-in-human-calls-much-needed-attention-to-clinical-trials/#762ce4fe6647

Clinical trial eligibility criteria a growing obstacle

despite a decade-long call for simplification of clinical trials, the number of criteria excluding patients from participating in clinical trials for lung cancer research continues to rise. Researchers found a nearly 60 percent increase in exclusion criteria by reviewing 74 National Cancer Institute-sponsored lung cancer trials from 1986 to 2016.

Read More: https://eurekalert.org/pub_releases/2017-08/usmc-cte081417.php

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FINANCIAL

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Mapi Pharma Ltd. Announces Closing of $10 Million Investment

Mapi Pharma Ltd., a privately held, fully integrated, clinical stage biopharmaceutical company has completed an investment round of $10 million by a Moon Fund. A Moon Fund is an Israeli investment firm focused on innovative Israeli healthcare and life science ventures, founded by Marius Nacht and Dr. Yair Schindel.

Read More: https://globenewswire.com/news-release/2017/08/17/1087060/0/en/Mapi-Pharma-Ltd-Announces-Closing-of-10-Million-Investment.html

Stony Brook wins $500,000 for drug development center

The cryo-electron microscope, the first of its kind on Long Island, will be used to "screen, model, engineer and manufacture new drugs and repurpose approved drugs for advanced therapeutic treatments," according to the grant application.

Read More: http://www.newsday.com/business/stony-brook-wins-500-000-for-drug-development-center-1.14069206

Deals Buzz: Two Genpact shareholders to offload 10 million shares

Aurobindo Pharma Ltd and Intas Pharmaceuticals Ltd are in the race to acquire part of the European assets of Israeli generic drugmaker Teva Pharmaceutical Industries Ltd in a deal that, if completed, could be the biggest overseas acquisition by an Indian pharma company, reports Mint. The process is being managed by Morgan Stanley and Bank of America Merrill Lynch (BAML) is expected to receive bids that are upwards of $1 billion. **Read More:** http://www.livemint.com/Companies/R36MWbESq4L4qtzO6uZ0dI/Deals-Buzz-Two-Genpact-shareholders-to-offload-10-million-s.html

Sun's profit crushed as it pays $150M to settle Provigil pay-for-delay case

Sun Pharma has been stung by a decade-old pay-for-delay lawsuit, one of a host of issues that contributed to a 74% slide in its profit last quarter for India's largest drugmaker, even after the litigation cost was backed out.

The drugmaker made the $150 million payment to resolve antitrust litigation in the U.S. over narcolepsy drug modafinil, a generic of Provigil. Mylan, which was also a defendant in the case, settled earlier this year for $96.5 million.**Read more at:** http://www.fiercepharma.com/pharma/sun-s-profit-crushed-as-it-pays-150m-to-settle-provigil-pay-for-delay-case

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MERGER & AQUISITION

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India: Aurobindo Pharma, Intas in race for Teva's European assets
Aurobindo Pharma Ltd and Intas Pharmaceuticals Ltd are in the race to acquire part of the European assets of Israeli generic drugmaker Teva Pharmaceutical Industries Ltd in a deal that, if completed, could be the biggest overseas acquisition by an Indian pharma company.
Read more at: https://www.dealstreetasia.com/stories/india-aurobindo-pharma-intas-teva-european-assets-80373/

Bidders line up for Teva's women's health unit in potential $2B sale
Teva is working to sell off its women's health unit to churn up cash and pay down debt, and it may have some takers.The assets have sparked interest from U.S. healthcare and consumer companies Church & Dwight Co. and Cooper Cos., Bloomberg reported, and they're weighing bids for part of Teva's women's health lineup.
Read more at: http://www.fiercepharma.com/pharma/bidders-line-up-for-teva-s-women-s-health-unit-final-offers-way-report

IEvolution Research Group adds San Antonio clinical trials company to its portfolio
Evolution Research Group owns and operates eight clinical research units across the country including units in Miami, St. Louis and San Diego. It is also part of a an affiliate network of 11 other clinical research sites. Read More: **Read more at:**
https://www.bizjournals.com/sanantonio/news/2017/08/10/evolution-research-group-adds-san-antonio-clinical.html

Shanghai Pharma signs deal with DHL to prepare for 'rapid global expansion'
Under the MOU, the pharma company – which generated revenues of more than $18 billion last year – will partner with DHL Supply Chain to enhance quality control measures, streamline distribution processes, and strengthen compliance with local and international food and pharmaceutical regulations.
Read More: https://www.thepharmaletter.com/article/shanghai-pharma-signs-deal-with-dhl-to-prepare-for-rapid-global-expansion

Eurofins Expands with Acquisition of DiscoverX
Eurofins Scientific (EUFI.PA) (Paris:ERF), a world leader in providing analytical support to the global pharmaceutical industry, announces that it has signed an agreement to acquire DiscoverX, a leader in drug discovery products and services across all stages of discovery from target identification and lead discovery to preclinical and beyond. The transaction is expected to close in the coming weeks, upon fulfillment of customary closing conditions.
Read More: https://patch.com/california/san-francisco/eurofins-expands-acquisition-discoverx

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SEP - Diesease Focus

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Sun Protection for Cancer Prevention

Types of Skin Cancer

Actinic keratosis is a common pre-cancerous lesion of the skin. Untreated, actinic keratoses can progress to squamous cell carcinoma.

Basal cell carcinoma, the most common skin cancer, is usually found on areas of the body that receive the most sun exposure, such as the scalp, face, arms and legs. This type of cancer is slow growing and infiltrates and destroys the surrounding tissue until it is removed.

Squamous cell carcinoma is the second most common type of skin cancer. It is primarily found on sun-exposed areas of the body. When left untreated, it can spread locally and occasionally metastasize

Melanoma, the most serious type of skin cancer but the least common, develops in the melanocytes. Exposure to ultraviolet radiation increases the risk of developing melanoma. Left untreated, this cancer can spread locally and is more likely to metastasize than any other skin cancer.

FDA Sunscreen Label Revisions and Updates

The FDA recently revised and updated sunscreen labeling. These updates should help consumers make the appropriate choice for their needs. The following are the new updates.

1. A sunscreen with SPF (Sun Protection Factor) 15 or higher and labeled as "broad spectrum" indicates that not only this sunscreen protects against sunburn, but can reduce the risk of skin cancer and premature skin aging if used as directed and with other sun protection measures.

2. Sunscreen products with an SPF value greater than 50 will be labeled only as "SPF 50+". The FDA does not have adequate data demonstrating that products with SPF values higher than 50 provide additional protection compared to products with SPF values of 50.

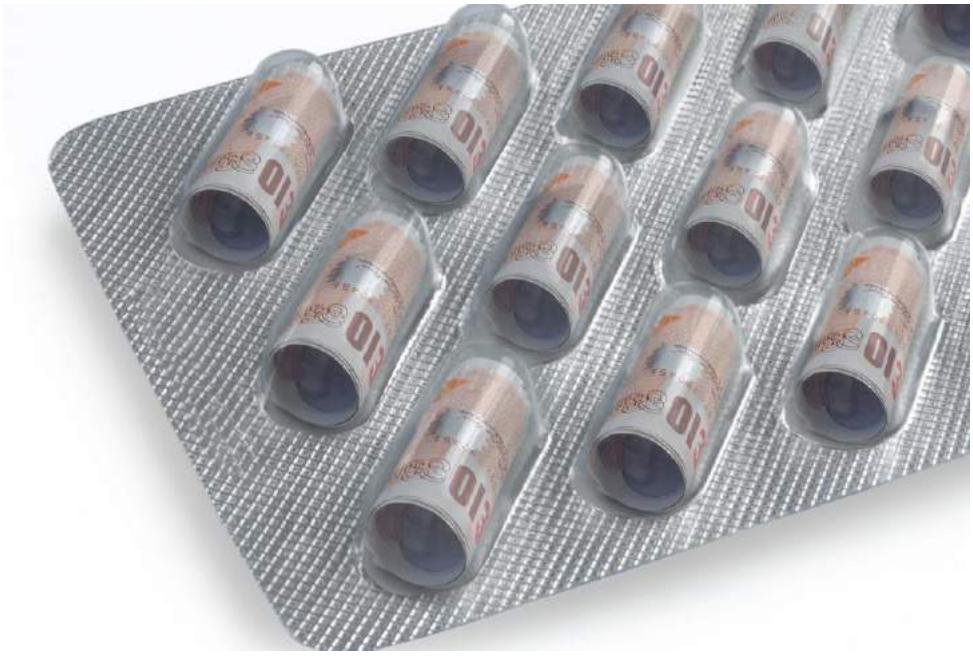
Read More: http://www.pharmacychoice.com/education/diseases/skincancer.cfm?disease=skincancer

Where's the relief from drug pricing fury?

As pharma spend continues to climb, so does public scrutiny on drug pricing. Once again, medicine manufacturers are spurred to strike a fair solution to balance raging its R&D appetites with affordable access to treatments for patients

Last year saw many pharma firms land in the spotlight over drug prices including the likes of Actavis UK, Pfizer and Mylan.

Research from the Kaiser Family Foundation h states that the percentage of individuals spending over $1000 out-of -pocket annually on medicines is rising. Prescription drug expenditure is predicted to hold its ascent.



Patients need to foot higher prices to get a newer patented drug in contrast to an older generic treatment. Some have even ventured to accuse some pharma firms of 'debranding' – hiking the price of generic medicines or even delaying the entry of a generic drug to prevent the loss of revenue.

The rising price points of medicines have spurred many payers to demand more controls. Pharma pricing models have advanced slightly over the years away from being depicted by market forces to the values being agreed by payers and pharma companies.

Read More: https://www.pharma-iq.com/market-access/articles/where%E2%80%99s-the-relief-from-drug-pricing-fury

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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:
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   Abhishek.patel@veedacr.com,

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