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The Veeda Newsletter

JAN 2018
ISSUE 01

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INDIAN PHARMA

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Indian R&D based pharma cos get 304 ANDA approvals in 2017.

Indian pharmaceutical companies and their subsidiaries received 304 final ANDA approvals from US FDA during 2017 as compared to 201 ANDA approvals in the previous year. The US FDA approved total 846 ANDA during 2017 which remained highest during last decade. Indian companies with enhanced R&D investments during last couple of years, managed to secured almost 36 per cent of total approvals by US FDA. Further,
Read more at: http://www.pharmabiz.com/NewsDetails.aspx?aid=106561&sid=1

2017 was a banner year for Indian science

2017 has been an exciting year for science in India. From unheralded incremental innovations to Big Bang headline-grabbing global feats, Indian scientists have done some very important work to push the frontiers of science this year.Indian researchers made significant contributions to R&D across a broad spectrum of fields spanning across space sciences to life sciences.
Read More: https://theprint.in/2017/12/31/2017-banner-year-indian-science-writes-kiran-majumdar-shaw/

India fast emerging as inventors' hub for drugs patent

India is fast emerging as an inventors' hub for patents for an assortment of drugs worldwide. Around 15 per cent of the total 1.3 lakh patents filed in India from 2013 to 2015 have been contributed by the indigenous pharmaceutical industry. India is ranked second only to the United States in terms of applications for product patent for drugs with the USFDA (US Food and Drug Administration) as revealed during the ongoing 69th Indian Pharmaceutical Congress taking place in Chandigarh.
Read More: https://health.economictimes.indiatimes.com/news/pharma/india-fast-emerging-as-inventors-hub-for-drugs-patent/62236584

Indian drug makers making inroads into new CNS treatments

Pharmaceutical companies in India have been providing scientific insights into the genetic causes and biological processes underlying neurodegenerative diseases, reports The Pharma Letter's India correspondent. Several pharmaceutical firms in India have been developing and delivering innovative therapies for people living with serious neurological and neurodegenerative diseases.
Read More: https://www.thepharmaletter.com/article/indian-drugmakers-making-inroads-into-new-cns-treatments

REGULATORY NEWS

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2017 saw record number of FDA approvals for drugs

The FDA approved 46 drugs in 2017, tying a record set for approvals in 2015. Cancer medications led the way, with 16 oncology and 11 hematology drugs approved.
Read More: https://www.healio.com/hematology-oncology/practice-management/news/online/%7Bd58386c5-b872-4234-8037-caac7c7effb1%7D/2017-saw-record-number-of-fda-approvals-for-drugs

FDA issues three guidance's, including long-awaited CDS guidelines

FDA Commissioner Scott Gottlieb dropped three new FDA guidance documents today, two draft guidances and a final guidance. One draft guidance is the long-awaited guidance on clinical (as well as patient) decision support, while the other deals with changes to medical software policy based on Congressional mandates in the 21st Century Cures Act.
Read More: http://www.mobihealthnews.com/content/fda-issues-three-guidances-including-long-awaited-cds-guidelines

USFDA vigil on Indian pharma companies to become more stringent

Indian pharma companies, that are already grappling with regulatory compliance issues, will now have to be ready for more inspections as the USFDA has tied up with eight EU member states.
Read More: http://www.moneycontrol.com/news/business/usfda-vigil-on-indian-pharma-companies-to-become-more-stringent-2463559.html

US FDA requests drugmaker input for nanoscale meds

The US FDA has released draft guidance for firms using nanomaterials in drug products, highlighting the "diversity" of nanoscale formulations.
Read More: HTTPS://WWW.IN-PHARMATECHNOLOGIST.COM/ARTICLE/2017/12/18/US-FDA-REQUESTS-DRUGMAKER-INPUT-FOR-NANOSCALE-MEDS

DCGI bans import of drug ingredients from six Chinese firms

Citing quality issues, India's drug regulator Drug Controller General of India (DCGI) has banned the import of ingredients of drugs from six major Chinese pharmaceutical firms.
The move, according to pharma lobby groups could have serious ramifications for the Indian pharma industry, even leading to possible shortages of antibiotics, and anti-diabetes, anti-psychotic and antacid drugs.
Read more at: http://www.livemint.com/Industry/p1oOgKmEARFLMWY02fB65H/DCGI-bans-import-of-drug-ingredients-from-six-Chinese-firms.html

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CLINICAL RESEARCH

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The Future of Clinical Trial Modernization: What's to Come in 2018.

2017 has been an exciting year for the clinical trials industry on many fronts, driven by new methods, regulation, and technology. The FDA has made advancements by laying out the foundation for digital health, patient centricity is evolving to include study site-centric approaches,

Read More: http://www.appliedclinicaltrialsonline.com/future-clinical-trial-modernization-what-s-come-2018

The First CRISPR Clinical Trial Could Begin in 2018

Officially submitted to European regulatory authorities, the application outlines a test of CTX001, a CRISPR treatment designed for patients with sickle cell disease and β-thalassemia. In an interview with Wired,

Read More: https://www.google.com/url?rct=j&sa=t&url=https://futurism.com/first-crispr-clinicaltrial/&ct=ga&cd=CAEYAioRNjQyMzY1MzEzMTAzOTI4MzMyGmRhMTE5NmUwMTM0NmJhNDA6Y29tOmVuOlVT&usg=AFQjCNFowpU_3xx7sg5BMUbyYVv_vgPeow

FDA opens door to multiarm, multicompany clinical trials

The FDA has outlined how developers of drugs targeting rare pediatric diseases can streamline their clinical development programs by collaborating. Officials want drug developers to consider teaming up to test multiple candidates in single trials, thereby cutting the number of patients who need to receive placebos.

Read More: https://www.fiercebiotech.com/biotech/fda-opens-door-to-multi-arm-multi-company-clinical-trials

New guidelines on clinical trial design for patients with brain metastases

central nervous system (CNS) or, if such patients were allowed on trial, trials have often failed to clearly capture information on the drug's effect in the brain. Today new guidelines from an international, multidisciplinary group published in the journal Lancet Oncology describe how to most appropriately address cancer patients with CNS involvement within clinical trials of anti-cancer drugs.

Read More: https://www.eurekalert.org/pub_releases/2017-12/uoca-ngo122817.php

FINANCIAL NEWS

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With 29% growth, Indian mkts end 2017 with a bang

The Indian market has rallied to be one of the top performing ones in the world in 2017. The reasons were several — easy availability of money globally, India's improving economic fundamentals, the government's demonstration of its serious intent for economic reforms, signs of a turnaround in corporate earnings and state poll results favouring the ruling BJP-led alliance.
Read More:https://timesofindia.indiatimes.com/business/india-business/with-29-growth-indian-mkts-end-2017-with-a-bang/articleshow/62301071.cms

India Inc sews deals worth $60 b in 2017 with big M&As

India Inc is looking at a huge M&A tally of over $60 billion (about ₹4 lakh crore) for 2017, helped by some marquee domestic deals and rich valuations for various private equity investments. The need to consolidate in the wake of financial stress, as also for cashing out from valuable businesses to meet debt obligations, will continue to give a further boost to the deal-making activities, experts feel.
Read More: http://www.thehindubusinessline.com/economy/india-inc-sews-deals-worth-60-b-in-2017-with-big-mas/article10004123.ece

Khaitan, CAM, Sidleys team up for $142.5m Natco Pharma QIP

In otherwise quiet pharma capital markets, leading pharmaceutical company, Natco Pharma has raised Rs 915 crores (approximately $142.5 million) through the issue of securities to qualified institutional investors, as reported by MoneyControl and The Economic Times. The board of directors earlier at their meeting held on November 2, 2017 had approved to raise up to Rs 1,500 crore through various modes of capital-raising including QIP, GDRs, FCCBs etc.
Read More: https://www.legallyindia.com/capital-markets/khaitan-cam-sidney-austin-team-up-for-142-5m-natco-pharma-qip-00011130-8937

India pharma exports to touch $20 bln by 2020: study

Indian pharmaceutical exports are likely to touch $20 billion by 2020 from the current level of around $16.5 billion, registering a compounded annual growth rate (CAGR) of about 30 per cent, reveals ASSOCHAM and UL India joint study.
Read More: http://www.business-standard.com/article/news-cm/india-pharma-exports-to-touch-20-bln-by-2020-study-117122100561_1.html

MERGER & AQUISITION

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'India Inc's November M&A deal tally grows 55% to $3 bn'

“India Inc's merger and acquisition activity registered a growth of 55 per cent year- on-year in November with deals worth USD 3.2 billion, powered by big-ticket transactions and revival in cross-border activity, says a report.
Read More:
https://economictimes.indiatimes.com/news/company/corporate-trends/india-incs-november-ma-deal-tally-grows-55-to-3-bn/articleshow/62036732.cms

Torrent Pharma completes acquisition of Unichem Laboratories Ltd

Torrent Pharmaceuticals Limited on Thursday announced that it has completed acquisition of branded business of Unichem LaboratoriesBSE 2.88 % Limited for India and Nepal, including its Sikkim manufacturing facility, on a going concern basis by way of slump sale. This transaction was in pursuance of the definitive binding agreement entered into between Torrent and Unichem on November 3, 2017. Read more at:
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/torrent-pharma-completes-acquisition-of-unichem-laboratories-ltd/articleshow/62066921.cms

Aurobindo, Dr Reddy's Laboratories frontrunners to buy out bankrupt Orchid Pharma.

Indian drug companies AurobindoBSE 0.87 % Pharma Ltd. and Dr Reddy'sLaboratories Ltd. are emerging as the frontrunners to buy out bankrupt Orchid Pharma Ltd. as they seek to expand their capacities. A key player in injectibles and active pharmaceutical ingredients (API) in its heyday,
Read More:
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/aurobindo-dr-reddys-laboratories-frontrunners-to-buy-out-bankrupt-orchid-pharma/articleshow/62110245.cms

Pharma 2018: Expect more M&As, USFDA reinspections in a normalized year

What is the outlook for Indian pharma in 2018? Analysts tend to think that it's a bit uncertain but many still feel the worst may be over. The last three fiscal years have been challenging for Indian pharma companies. The year 2015/16 saw price regulations being rung in by the pricing regulator. The next fiscal, 2016/17, was also tumultous with the demonetisation drive of the Modi government while 2017/18 has seen businesses coming to terms with the switchover to the Goods and Services Tax (GST) regime.
Read More: http://www.businesstoday.in/sectors/pharma/pharma-2018-expect-m-and-as-usfda-re-inspections-normalized-year-despite-domestic-uncertainties/story/266876.html

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ARTICLE OF THE MONTH

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Innovative approached to informed consent for randomized clinical Trials: Identifying the ethical challenges.

At least since issuance of the Nuremberg code in 1947, there has been debate over the ethics of informed consent and what do participants need to consent and what do they need to consent to? Many guidelines, policies, and commentators attempt to answer these questions by comparing clinical research to clinical care and mandating informed consent for the difference. This approach, like comparison more generally has the potential to illuminate the important differences and also to exaggerate them. It has illuminated the importance of disclosing to potential participants that enrollment in research involves contributing to a project to help others. It has also encouraged the view that the many differences between research and care are necessarily contrary to participants clinical interests: hence, they all must be disclosed to potential participants. The result is consent for clinical research has become complicated and burdensome.

The present two proposals, Just-in-time consent and trials within Cohorts, aim to simplify the consent process by leveraging the fact that clinical trials often include standard of care arms. The statistician, Marvin Zelen, famously started with the same thoughts and proposed to randomize participants first and then obtain their consent for the option to which they had been randomized. Individuals randomized to the experimental arms would provide consent for research, while those randomized to the control arm would provide standard clinical consent.

READ MORE & SOURCE:
http://journals.sagepub.com/doi/full/10.1177/1740774517746621

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UPCOMING CONFERENCE

1. Outsourcing in Clinical Trials West Coast 2018

Feb 21 - 22 2018,
Burlingame,California , USA

2. DCAT WEEK '18

Mar 19-22 2018,
NY, USA

DCAT Week
March 19–22, 2018
New York City

For Inquiry & Meeting Appointment please mail us at info@veedacr.com

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