The Veeda Newsletter

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Expanding Global Reach and Capabilities

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VEEDA NEWS

A Our experts at DCAT Week 2024

We are excited to share a glimpse of our team who attended DCAT Week 2024 to discuss drug development of generics, complex generics, and innovator drug molecules with various global pharma and biopharma companies.

Know More!

Our R&D laboratories get DSIR approval

The DSIR certification from the Ministry of Science and Technology, Government of India, is an important milestone in the journey of Veeda's biopharma division, as this will further catalyze faster commercialization of lab-scale R&D for our clients and help us strengthen its consultancy & technology management capabilities to facilitate scientific and industrial research.

Know More!

Women's Day Celebration at Veeda

This International Women's Day, we celebrated the incredible women of Veeda Group with a special event featuring a keynote address by Dr. Mahesh Bhalgat, Veeda Group CEO, followed by insightful speeches from esteemed external speakers: Dr. Jharna Pathak (Associate Professor at Gujarat Industrial Development Research & External Member on Veeda POSH committee) and Ms. Roopa Dave (Expert Dietician).

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Telangana DCA carries out raids & seizes illegally procured insulin injections worth Rs. 52 lakhs

After the last week's raid in a house of a drug addict in Sainikpuri where narcotic drugs were used to be diverted by an ENT surgeon from Jagtial, the officials of the Telangana DCA seized Rs. 52 lakh worth of illegally procured insulin injections from six wholesalers' premises in Hyderabad, in other raids which lasted for six days. The confiscated products, which were sold on 40 per cent discounts in the retail market, were procured illegally from New Delhi without purchase bills. A pre-filled pen worth Rs. 5,263 was being offered for sale at Rs. 2,070 by the wholesaler. Since it seemed unusual it raised concerns about its authenticity, sources from the DCA informed. The office of the director general of the drugs control administration has informed that the government is now concerned about the authenticity of the detected insulin injections. The officials seized stocks worth a total of Rs. 52 lakhs in the raids. According to information received from the DG's office in Hyderabad, the raids were continuing from March 15 to 20.

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DCC recommends inclusion of revised GDP guidelines in D&C Rules

The Drugs Consultative Committee (DCC) has recommended that revised Good Distribution Practices (GDP) guidelines for pharmaceutical products, which is currently under preparation, should be made part of the Drugs and Cosmetics Rules, 1945 to ensure proper implementation across the supply chain. In a latest meeting of the Committee, the drug regulatory experts from across the country discussed the proposal to make guidelines on GDP under separate schedule to the D&C Rules, 1945. Currently, the non-mandatory nature of these guidelines has led to manufacturers not ensuring the maintenance of storage conditions of drugs during transit to the wholesale and retail levels. "DCC agreed that revised Good Distribution Practices (GDP) guidelines should be circulated to all States/Union Territories before finalising and once it is finalised, it should be made part of the Rules to provide legal backing..." said the Committee. Accordingly, DCC recommended for inclusion of the GDP guidelines in the D&C Rules, 1945.

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Health ministry removes pack size provisions for two chest pain formulations from Schedule P1

Merck, known as MSD outside of the United States and Canada, announced the US Food and Drug Administration (FDA) has accepted for priority review a new supplemental Biologics License Application (sBLA) seeking approval for Keytruda, Merck's anti-PD-1 therapy, in combination with standard of care chemotherapy (carboplatin and paclitaxel), followed by Keytruda as a single agent for the treatment of patients with primary advanced or recurrent endometrial carcinoma. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action, date of June 21, 2024.

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Central & state DCAs need to become more pro-active in dealing with spurious drugs menace: Ex-DCGI

The Central and state drugs control authorities (DCAs) have to become more pro-active in the surveillance system, but in the same way the governments should support them with sufficient staff and adequate protection cover to unravel the illicit and spurious drug manufacturing and marketing activities in clandestine locations in the country, according to former Drugs Controller General of India (DCGI), Dr. Surinder Singh. Without blaming anybody for the recent raid and seizure of spurious drugs from different parts of the country by state regulators with the help of police personnel, he said there is lack of intelligence and surveillance on the part of both the drug law enforcement agencies and both are responsible for the lapses.

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FOPE seeks its inclusion into Committee for Reforms in the Pricing Framework

The Federation of Pharma Entrepreneurs (FOPE) is keen to play an active role as a representative in the recently constituted Committee for Reforms in the Pricing Framework. In this regard, it has communicated to the Department of Pharmaceuticals, requesting it to be included as special invitee representing the micro, small and medium pharma enterprises (MSMEs) in the country. In a letter to the government, FOPE spelt out that changes in pharmaceutical pricing mechanisms can have broad implications across the industry. It disproportionately affects MSME manufacturers due to their limited resources and market position. Therefore, it is crucial for policymakers to consider the potential impact on these enterprises and implement measures to support their viability and competitiveness within the market.

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Revenue for Ind-Ra rated hospitals is likely to grow 12%-13% yoy in FY25

Maintaining a neutral outlook for the corporate healthcare sector for FY25, Fitch Group's India Ratings and Research (Ind-Ra) forecasts that the revenue of the hospitals rated by the agency is set to grow 12-13 per cent year-over-year (yoy) during the financial year. The growth is expected to be driven by continued growth in healthcare needs and higher average revenue per occupied bed (ARPOB), revenue from medical tourism, occupancy and prices. The outlook for hospitals is supported by continued robust demand drivers, a sustained improvement in profitability, and calibrated capacity enhancement capex, which would jointly lead to a comfortable liquidity position and help sustain the credit profile improvement.

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India's pharma market maintains 10% growth despite disruptions; set for 8-10% growth with price hikes, new launches, HDFC sec report

The India Pharma Market (IPM) has emerged as a strong growth story with a steady around 10% Compounded Annual Growth Rate (CAGR) over the fiscal years 2012 (FY12) to 2023 (FY23), despite various disruptions in the marketplace, revealed a report on the domestic formulation sector from stock broking company HDFC securities. According to Mehul Sheth, Research Analyst at HDFC securities, the growth of the IPM is attributable to a volume expansion of 5-10% during FY12-18, which slowed down to 2-3% from FY19-23 due to increased generic competition.

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Venus Remedies gets its first incentive of Rs 7.50 crore under PLI scheme

Venus Remedies Ltd, one of India's key manufacturers of generic drugs, on Wednesday announced that it has been awarded its first disbursement of Rs 7.5 crore under the Central government's Production Linked Incentive (PLI) scheme for the financial year 2022-23, which covers 75 percent of the total incentive due to the company for the year. According to the company's press statement, having been selected as one of the few pharmaceutical companies under the PLI scheme in December 2021, Venus Remedies has since embarked on a journey to amplify its manufacturing infrastructure and expand its product portfolio.

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Dr Reddy's gets Rs 74.22 cr tax demand from GST authority

Pharma major Dr Reddy's Laboratories Ltd on Tuesday said it has received a tax demand with penalty totalling more than Rs 74.22 crore from GST authority for wrongly availing of credit of input tax. In a regulatory filing, the company said it has received an order seeking demand, including interest and penalty, from the Additional Commissioner of Central Tax, Hyderabad GST Commissionerate. The authority has passed the order on the contention that the company has wrongly availed of input tax credit, or not reversed the input tax credit under provisions of CGST/TGST/IGST Act, 2017, it added. The tax amount is Rs 67,47,37,495, while interest will be as applicable rates on tax demand, the company said, adding that the penalty is Rs 6,74,73,752.year.

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Supriya Lifescience expects to double revenue to Rs 1,000 crore in next 3 years

Mumbai, Pharma company Supriya Lifescience expects to double its revenue to Rs 1,000 crore in the next three years by venturing into higher-margin earning niche segments next fiscal, a senior company executive has said. The city-based Active Pharmaceutical Ingredient (API) maker is expanding its product basket by entering the oral solid dosages (OSD), liquid inhalers and injectibles for which a new facility, with an investment of around Rs 60 crore, is coming up at Ambernath near the megapolis. Apart from this, the company is expanding its existing product basket by adding six to seven molecules targeting anti-anxiety, anesthesia and anti-diabetes. It is also diversifying into contract manufacturing services, which could potentially boost margins by 4-5 percentage points, Wagh said. He added that after reaching full operational capacity, this can double the top line to Rs 1,000 crore by FY27

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CLINICAL RESEARCH

Merck announces positive data from multiple phase 3 studies of V116, an investigational, adult-specific 21-valent pneumococcal conjugate vaccine

Merck, known as MSD outside of the United States and Canada, announced positive data from multiple phase 3 studies evaluating V116, the company's investigational, adult-specific 21-valent pneumococcal conjugate vaccine, at the 13th Meeting of the International Society of Pneumonia and Pneumococcal Diseases (ISPPD) in Cape Town, South Africa. Across the clinical studies presented, V116 was shown to be immunogenic for all 21 serotypes covered by the vaccine in a variety of adult populations, including those who had not previously received a pneumococcal vaccine (pneumococcal vaccine-naïve), those who had previously received a pneumococcal vaccine (pneumococcal vaccine-experienced) and those with an increased risk of pneumococcal disease, including people living with human immunodeficiency virus (HIV).

MERCK

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Bill & Melinda Gates Medical Research Institute begins phase 3 trial of tuberculosis vaccine candidate

The Bill & Melinda Gates Medical Research Institute (Gates MRI) announced that a phase 3 clinical trial to assess the efficacy of the M72/AS01E tuberculosis (TB) vaccine candidate is now underway, with first doses given in South Africa, where TB takes a heavy toll. If shown to be well-tolerated and effective, M72/AS01E could potentially become the first vaccine to help prevent pulmonary TB in adolescents and adults, the most common form of the disease, and the first new TB vaccine in over a century. Globally, according to the World Health Organization, an estimated 10.6 million people fell ill with TB in 2022 and 1.3 million died — over 3,500 people per day.

BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE

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DUO-E phase III trial of Lynparza & Imfinzi demonstrates strong clinical benefit and more than doubled median duration of response vs. chemotherapy in patients with pMMR advanced or recurrent endometrial cancer

Latest analysis of the results from the DUO-E phase III trial showed Imfinzi (durvalumab) plus platinum-based chemotherapy followed by Imfinzi plus Lynparza (olaparib) (Lynparza and Imfinzi arm) demonstrated an improvement in multiple key secondary efficacy endpoints, particularly in patients with mismatch repair proficient (pMMR) advanced or recurrent endometrial cancer compared to chemotherapy alone.

AstraZeneca

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Bayer announces positive results from phase III study OASIS 3 of elinzanetant for moderate to severe vasomotor symptoms

Bayer announced positive topline results of the phase III study OASIS 3 evaluating the efficacy and long-term safety of the investigational compound elinzanetant versus placebo. In this study, elinzanetant successfully met the primary endpoint demonstrating statistically significant reduction in the frequency of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) from baseline to week 12 compared to placebo. The long-term safety profile observed over 52 weeks in the OASIS 3 study is overall consistent with previously conducted studies and published data on elinzanetant.

BAYER

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GSK presents positive results from RUBY phase III trial of Jemperli to treat primary advanced or recurrent endometrial cancer at SGO 2024 meeting

GSK plc announced statistically significant and clinically meaningful overall survival (OS) results from Part 1 and progression-free survival (PFS) results from Part 2 of the RUBY/ENGOT-EN6/GOG3031/NSGO phase III trial in adult patients with primary advanced or recurrent endometrial cancer. These data were presented in a late-breaking plenary session at the Society of Gynecologic Oncology 2024 Annual Meeting on Women's Cancer (16-18 March). The goal of the RUBY phase III trial programme is to evaluate which patients with primary advanced or recurrent endometrial cancer could potentially benefit from treatment with Jemperli (dostarlimab) plus chemotherapy, with or without the addition of Zejula (niraparib) maintenance.

GSK

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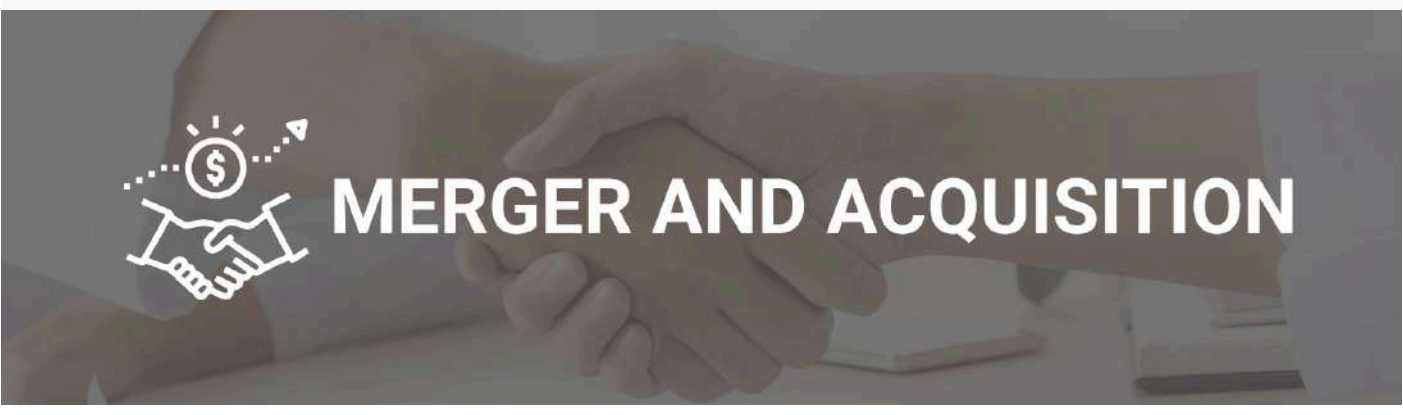

Roche announces Lonza to acquire Genentech manufacturing facility in Vacaville, California for USD 1.2 billion

Roche announced that it has entered into a definitive agreement with Lonza, under which Lonza will acquire the Genentech manufacturing facility in Vacaville, California, USA, for USD 1.2 billion in conjunction with a manufacturing agreement and related quality services and warehousing. Under the terms of the agreement, the approximately 750 Genentech employees at the Vacaville facility will be offered employment by Lonza and the products currently produced at the site by Roche will continue to be supplied by Lonza for a transition period.

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Roquette to acquire New York-based excipients producer, IFF Pharma Solutions

Roquette, a global leader in plant-based ingredients and pharmaceutical excipients, announced an agreement to acquire IFF Pharma Solutions, a worldwide producer of excipients for oral dosage solutions, to reinforce its position as a major partner to the pharmaceutical industry. The combination of the two complementary businesses will rebalance the company's portfolio around the two pillars of health and nutrition. It will expand its pharma product range and significantly accelerate Roquette's growth.

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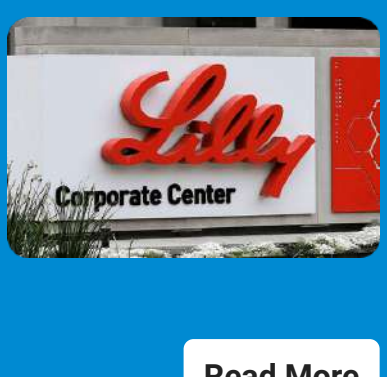
Eli Lilly partners with Amazon Pharmacy to deliver GLP-1 drugs

Amazon Pharmacy will now be filling prescriptions for glucagon-like peptide-1 (GLP-1) drugs — and other pharmaceuticals for obesity, diabetes, and migraines — requested through Eli Lilly's LillyDirect platform, according to an announcement by Lilly on March 13, 2024. The pharmacy will join TruePill as one of the platform's prescription-filling entities



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ChromaCode partners with Medical College of Georgia on rapid testing for critical biomarkers in NSCLC

ChromaCode, Inc, a pioneering genomics multiplexing platform company developing accessible and affordable lab-based solutions, has announced a partnership with Department of Pathology, Medical College of Georgia, to test the analytical and clinical performance of ChromaCode's HDPCR non-small cell lung cancer (NSCLC) biomarker assay. The NSCLC assay has complete coverage of variants identified by the National Comprehensive Cancer Network (NCCN) as clinically relevant in NSCLC and offers a four hours workflow for rapid results, while simplifying results interpretation which is performed in minutes through cloud-based analysis.

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AstraZeneca acquires Fusion Pharmaceuticals in $2 billion deal

AstraZeneca entered into a definitive agreement to acquire Fusion Pharmaceuticals in a $2 billion deal. Through this deal, AstraZeneca will expand its portfolio and gain access to Fusion's clinical-stage, next-generation radioconjugates and research that have been used in oncology treatments. According to the American Chemical Society (ACS), radioconjugates have emerged as a critical tool in oncology. They combine a targeting agent to identify cancer cells with cancer-killing radioactive isotopes. By acquiring Fusion Pharmaceuticals, AstraZeneca will add multiple radioconjugates to its portfolio, including Fusion's most advanced radioconjugate, FPI-2265.

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Japanese majors Toyota Tsusho & Secom to set up second multi-super specialty hospital in India for Rs. 1,000 crore

In its continuous pursuit to provide quality healthcare to larger communities, Sakra World Hospital announced its visionary plan for a new state-of-the-art facility in Bengaluru recently. The occasion marked the 10th anniversary celebrations of the pioneering MNC hospital group. Sakra is India's first 100% FDI multi-super specialty hospital powered by Japanese innovation and technology through a collaboration between healthcare major Secom Medical System and trading conglomerate Toyota Tsusho. Situated in Marathahalli on the Outer Ring Road in Bengaluru, Karnataka, it is a 350-bed hospital that offers medical treatment in all areas, including emergency and trauma care, cardiac sciences, digestive and hepatobiliary sciences, renal science, rehabilitation, orthopaedics, women's and children's health, and neurosciences.

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Pharmexcil DG urges member companies to avail revamped PTUAS Scheme

The Pharmaceuticals Export Promotion Council of India (Pharmexcil)'s director general (DG) Uday Bhaskar has urged its member companies to actively participate in the recently revamped Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) and reap the benefits of incentivization. This revamped PTUAS scheme is expected to provide a significant boost to MSME manufacturers in the pharmaceutical sector, empowering them to elevate their standards and compete effectively on the global stage. With its focus on quality enhancement and capacity building, the scheme aligns with the broader objective of fostering innovation and excellence within the pharmaceutical industry.

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Gleneagles Healthcare India unveils new name and identity to advance clinical excellence and patient care

Gleneagles Healthcare India, one of India's leading healthcare providers, has announced a transformative rebranding initiative across its six hospitals located in Mumbai, Chennai, Bengaluru, and Hyderabad. These hospitals are now unified under the new identity of 'Gleneagles Hospitals,' a signature international brand of IHH Healthcare. The launch of its new identity, along with refreshed visitor touchpoints including hospital entrances and reception areas, reflects Gleneagles Healthcare India's dedication to providing patient-centric care, leveraging IHH's global expertise and best practices.

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Egg freezing revolutionized as EPIA's new clinic gives women the power to pause biological clock

EPIA, a pioneering women's healthcare early-age start up, introduces its first fertility and wellness clinic in the heart of New Delhi. Its patient-centric clinic underscores EPIA's commitment to providing comprehensive reproductive health solutions through state-of-the-art facilities and unique services. The clinic offers affordable egg-freezing facilities utilizing cutting-edge techniques and FDA-approved drugs. It enables fertility preservation for women who decide their motherhood timing on their terms. EPIA also provides fertility treatments, gynaecological care, wellness support, and a holistic approach to women's health.

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ARI plays crucial role in contributing to clinical research sector

India has witnessed a significant boom in clinical research over the past few years. Several factors including cost-effective conduct of clinical trials, large and diverse patient pool, skilled workforce, streamlined regulatory processes, infrastructure development and international collaboration have contributed to its overall growth and positioning the country as a key player in global research initiatives. India has become an attractive destination for global conglomerates in pharmaceuticals, biotechnology and medical devices seeking to conduct clinical trials. In this dynamic landscape, Apollo Research and Innovations (ARI), the research division of Apollo Hospitals plays a crucial role in contributing to the clinical research industry. ARI focuses on scouting, evaluating, deploying, and integrating innovations across Apollo Hospitals. The vision of ARI is to foster innovation in technology, therapy, processes, and business models to achieve greater access, affordable costs, and global quality standards. Some of the key areas of innovation include the convergence of healthcare with life sciences & technology, innovation in software, medical devices & public health.

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