The Veeda Newsletter

JULY 2023: ISSUE 07

Partners in Creating

a healthier tomorrow

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Our Latest case study on Long-acting Injectable Pharmacokinetic Studies

Read to find how Veeda assisted a US-based company conduct a Bioequivalence Study for an Antipsychotic LAI drug candidate, helped navigate these challenges, and contributed to the advancement of LAI medication for improved patient care in the Psychiatry therapy area.

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Latest Scientific Poster on Ferric Carboxymaltose Formulation

Read our recent Scientific Poster by our Bioanalytical team, representing a Novel Approach for the Quantitation of Total Iron and Transferrin-bound Iron in Human serum samples by using ICP-OES.

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Our team at the International Conference on Pediatric Drug Development in South Asia

Representing Veeda, Dr. Kiran Marthak (Director) chaired an all-important interactive panel discussion on Pediatric Drug Development, which featured interesting views and conversations.

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CDSCO Flags 48 Drugs On Quality, Drugs From Alkem, Cadila Pharma

Central Drugs Standard Control Organization (CDSCO) has flagged 48 medicine batches that failed to qualify for a random drug sample test for June, while one drug sample has been declared spurious.The list of Drugs declared as Not of Standard Quality includes cholesterol reduction tablets Rosuvastatin and Vitamin D3 Tablets manufactured by Synokem Pharmaceuticals (Batch No.22S1GTA576), Prednisolone Tablets manufactured by Unicure India (Batch No.PDT1009).

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EMA expands OPEN framework to a wider range of medicines

EMA has expanded the scope of the OPEN initiative from Covid-19 vaccines and treatments to a wider range of medicines, such as medicines with the potential to address antimicrobial resistance (AMR), respiratory syncytial virus (RSV) infections or newly diagnosed myelodysplastic syndromes (and other hereditary diseases).OPEN was established by EMA in December 2020 as a framework to increase international collaboration and share scientific expertise on the evaluation of Covid-19 vaccines and therapeutics, initially as a pilot.

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DCGI in talks with global consultants to rationalise drug regulations to ensure quality

In order to achieve quality, compliance and patient safety, the Central Drugs Standard Control Organisation (CDSCO) is rationalising the drug regulations in consultation with global regulatory experts. This, according to the Drugs Controller General of India (DCGI) Rajeev Singh Raghuvanshi, will be done towards ease of doing business and developing a quality culture.Speaking on the sidelines of a panel discussion on Quality, Compliance and Patient Safety at the 9th International Pharmaceutical Exhibition (iPHEX) in Hyderabad, the DCGI said this is very much required as the pharma industry is projected as a US$ 500 billion opportunity by 2047.

DCGI
Drug Controller General (I)

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FDA Converts Novel Alzheimer's Disease Treatment to Traditional Approval

The U.S. Food and Drug Administration converted Leqembi (lecanemab-irmb), indicated to treat adult patients with Alzheimer's Disease, to traditional approval following a determination that a confirmatory trial verified clinical benefit. Leqembi is the first amyloid beta-directed antibody to be converted from an accelerated approval to a traditional approval for the treatment of Alzheimer's disease. The drug works by reducing amyloid plaques that form in the brain, a defining pathophysiological feature of the disease.

FDA U.S. FOOD & DRUG ADMINISTRATION

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Global regulators confirm good safety profile of COVID-19 vaccines

EMA has just endorsed a joint statement on the safety of COVID-19 vaccines issued by the International Coalition of Medicines Regulatory Authorities (ICMRA).Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide shows that these vaccines aimed at protecting people from severe outcomes of COVID-19 have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women. The vaccines have saved millions of lives worldwide by significantly reducing the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2.

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Volume of India's pharma production to triple by 2035, turnover to grow by three-fold: DCGI

The Drug Controller General of India (DCGI) has stated that the volume of India's pharmaceutical production will triple in the next 12 years and the turnover of all companies will increase by threefold in another 10 years. The only thing necessary for the expected growth is that the entrepreneurs must be ready to take the challenges ahead.Dr. Rajeev Singh Raghuvanshi, the DCGI, was addressing the drug manufacturers of Tamil Nadu in the recently concluded pharma trade fair, Pharmac South in Chennai on July 15.

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Indian pharma market will touch US$ 130 billion by 2030: Dr S V Veeramani

India's pharmaceutical market is growing at a healthy rate and is expected to touch 130 billion USD by 2030, said Dr. SV Veeramani, chairman of the Pharmaceuticals Export Promotion Council of India (Pharmexcil) while delivering the keynote address at the Pharmac South Expo 2023 in Chennai on July 14.He said the industry's goal can be easily achieved because India has around 2000 WHO-GMP approved drug manufacturing plants as well as a lot of US FDA and EU approved plants.

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Structured Alpha LP to acquire all issued and outstanding common shares of Liminal BioSciences

Liminal BioSciences Inc. and Structured Alpha LP (SALP), a fund managed by Thomvest Asset Management Ltd., announced that they have entered into a definitive arrangement agreement (the Arrangement Agreement) under which SALP will acquire all of the issued and outstanding common shares of Liminal BioSciences (the Common Shares) that it does not already own.Under the terms of the Arrangement Agreement, Liminal BioSciences shareholders (other than SALP and its affiliates or associates) will receive US$ 8.50 in cash per Common Share, which represents a premium of approximately 135% over Liminal BioSciences' closing share price on the Nasdaq Capital Market on April 4, 2023

Liminal BioSciences

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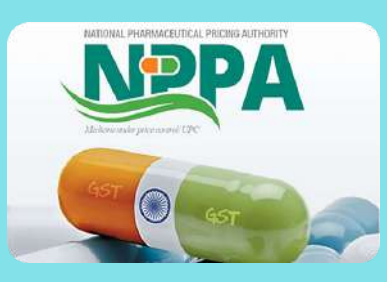
NPPA fixes ceiling price of two formulations, retail prices of 51 new drugs

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price of two anticoagulant formulations and the retail price of 51 new drugs after considering representations on the price fixation by the stakeholders.The Authority has considered the representations received from the companies on two formulations - dabigatran capsule 110 mg and dabigatran capsule 150 mg, which were newly added to the revised Schedule I of the Drugs (Prices Control) Order, 2013, after inclusion of the National List of Essential Medicines (NLEM), 2022 into the Schedule.Dabigatran is a drug used for the treatment of blood clotting in various body parts, such as the deep vein thrombosis and pulmonary embolism, among others. The Authority fixed the ceiling price of dabigatran 110 mg at Rs. 31.81 per capsule and dabigatran 150 mg at Rs. 35.59 per capsule.



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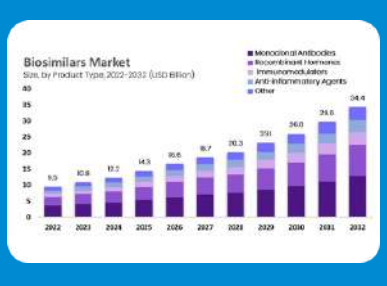
Biosimilars And Biologics Market is likely to hold a valuation of US$ 95,021.37 Million by 2032 at a CAGR of 15.5%

The Biosimilars And Biologics Market is expected to grow at a CAGR of 15.5% during the period 2022-2032. The market is valued at US$ 22,490.62 Mn in 2022 and is expected to reach a valuation of US$ 95,021.37 Mn by 2032.FMI, in its business report, elaborates the historical and current scenario of the global Biosimilars and Biologics Market in terms of production, consumption, volume, and value. The report scrutinizes the market into various segments, regions and players on the basis of demand pattern and growth prospects.



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ICMR soon to begin research on use of stem cell therapy in specific medical disorders

The Indian Council of Medical Research (ICMR) will soon begin research for generating evidence on use of stem cell in therapy in orthopaedic disorders, neurological disorders, ophthalmologic disorders, cardiac disorders, microvascular/surgical disorders, paediatric disorders, respiratory disorders, dermatologic disorders, endocrinologic disorders and gastroenterologic/hepatologic disorders.It has now invited Expression of Interest (EoI) from academicians and scientists to conduct the research. Starting date for the EoI is July 27, 2023 and the last date for submission of proposal is August 25, 2023 followed by review and selection on September 15, 2023.

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Omega-3 fatty acids appear promising for maintaining lung health: Study

Omega-3 fatty acids, which are abundant in fish and fish oil supplements, appear promising for maintaining lung health, according to new evidence from a large, multi-faceted study in healthy adults supported by the National Institutes of Health (NIH). The study provides the strongest evidence to date of this association and underscores the importance of including omega-3 fatty acids in the diet, especially given that many Americans do not meet current guidelines. Funded largely by the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, the study results were published in the American Journal of Respiratory and Critical Care Medicine.

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Bioluminescent bacteria coordinate signalling to colonize squid's light organ: Study

Bioluminescent bacteria and the Hawaiian bobtail squid have formed a longstanding mutually beneficial relationship. How the bacteria coordinate their behaviour to colonize the squid — through cellular signalling and cues from the environment — is detailed in a new study led by Penn State researchers.A paper describing the study is available online in the journal eLife. The researchers also show that the mechanism that they describe is likely to be widespread in a broad array of bacteria and that understanding this coordination of cellular signalling will be important for understanding how bacteria colonize their hosts more generally.

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Researchers at IISc develop fluorogenic probe to detect enzyme linked to early stage of Alzheimer's disease

Researchers at the Indian Institute of Science (IISc) have developed a fluorogenic probe to detect enzyme linked to early stage of Alzheimer's. Currently techniques deployed to detect manifestations of Alzheimer's disease are MRI, PET, and CT scans. These are seen to be complex, expensive, and often producing inconclusive results.Brain cells or neurons secrete neurotransmitters for signalling molecules that instruct other cells to perform certain functions. Acetylcholine (ACh) is one such neurotransmitter; its levels in the nervous system are controlled by enzymes like AChE, which breaks it down into two parts: acetic acid and choline.

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Raya Therapeutic enters early-stage R&D collaboration with argenx

Raya Therapeutic Inc., (Raya), a mission-driven company focused on the treatment of neurodegenerative diseases, has entered into an early-stage R&D collaboration with argenx. The collaboration focuses on testing combinations of Raya's pipeline of targeted small molecules with a potentially complementary product from argenx."We are delighted to be entering this early-stage R&D collaboration with argenx. argenx is one of the industry's most exciting companies, and their belief in our pipeline is an important validation for us.

RAYA THERAPEUTIC

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Sosei Heptares acquires Idorsia's pharmaceuticals business in Japan and APAC (ex-China)

Sosei Group Corporation, a fully integrated biopharmaceutical company, announces that it has resolved, at a meeting of the board of directors held on 20 July 2023, to acquire from Idorsia Ltd and Idorsia Pharmaceutical Ltd (together "Idorsia") all shares of Idorsia Pharmaceuticals Japan Ltd ("IPJ") and Idorsia Pharmaceuticals Korea Co., Ltd ("IPK") (the "Transaction").The strategic Transaction also includes the Japan and APAC (ex-China)1 territory rights to an exciting pipeline of medicines from Idorsia's portfolio, with lead product Pivlaz (clazosentan) already commercially available and with fast-growing sales in Japan following a successful launch in April 2022.

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Catalyst Pharma acquires exclusive North American license for vamorolone for DMD from Santhera Pharma

Catalyst Pharmaceuticals, Inc. announced the completion of its acquisition from Santhera Pharmaceuticals Holdings (Santhera) of an exclusive license for North America for vamorolone, a potential treatment for patients suffering with duchenne muscular dystrophy. The license is for exclusive commercial rights in the US, Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities. Additionally, Catalyst will hold North American rights for any future approved indications of vamorolone.

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BioIVT acquires Carlsbad, California-based provider of biospecimens for neurology and oncology research, PrecisionMed

BioIVT, a global research partner and biospecimen solutions provider for drug and diagnostic development, announced that it has acquired PrecisionMed, LLC, a leading supplier of high-quality human biological material for genetics, drug discovery, and biomarker research and in vitro diagnostics.Based in Carlsbad, California, PrecisionMed has been collecting biospecimens for neurology and oncology research for more than 27 years, and it has the largest private, global repository of longitudinally collected human CSF for scientific research. Its collection contains both normal and diseased CSF samples together with other matched biofluids, such as plasma, sera, and whole blood.

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Stada acquires leading local and regional consumer healthcare brands from Sanof in European countries

Stada is significantly expanding its European Consumer Healthcare portfolio by acquiring another range of well-established and leading local and regional consumer healthcare brands from Sanofi in European countries, including Belgium, Germany, Hungary, Spain and the United Kingdom, as well as Nordic countries.The transaction covers several brands, including: Antistax for pain relief and tiredness in legs; the allergy eye drops Lomudal; Omnivit vitamins; and Opticrom allergy eye drops. In addition, the two painkillers AAS and Dolalgial, as well as Bila-Git for gallbladder complaints, are part of the acquired portfolio. The transaction will be financed with a combination of cash on balance sheet and existing facilities, and is scheduled to close in the fourth quarter of 2023, subject to customary approvals of relevant regulatory authorities.

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Biocon Biologics completes acquisition of Viatris, expands footprint in emerging markets with biosimilars

Biocon Biologics, a subsidiary of Biocon announced the deal closure of Viatris that commenced in in November 2022. This marks the first wave of countries where Viatris' operations have fully transitioned to Biocon Biologics.The Bengaluru-based company has completed the integration of the acquired biosimilars business in over 70 countries in emerging markets effective July 1, 2023, increasing the scale and scope of its business. A robust integration plan has ensured a seamless transition of partners, people, systems, and processes across these countries.

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PredOmix to launch its women-specific cancer test in the second quarter of 2023

PredOmix is currently preparing for the commercial market launch of its women-specific cancer test which is planned for the latter part of the second quarter of 2023. The test will cover breast, endometrial, cervical, and ovarian cancers, informs Dr. Kanury V S Rao, co-founder, and chief scientific officer of PredOmix.He further said that the company is in the process of obtaining Drugs Controller General of India (DCGI) certification. This certification underscores the company's commitment to meet rigorous regulatory standards and ensures the quality and reliability of its screening tests.

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India's rising profile in clinical trials sparks urgency to raise public awareness: GlobalData

There is an urgent need for the pharma companies to work on increasing the public awareness regarding clinical trials, as the country is emerging as a key destination for clinical trials due to its large, diverse population and liberalised regulatory landscape, says GlobalData, a leading data and analytics company.Despite the increase in the number of clinical trials initiated by either domestic or multinational pharmaceutical companies in recent years, awareness about the trials is low. Addressing the issue through strategic approaches is a pressing need.

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Indian pharma industry wants to end multiple inspections by US FDA that results in long timelines for market approval

Emphasizing the need for more transparency in Good Manufacturing Practices (GMP) inspection being conducted, the Indian pharma industry has recommended doing away with multiple levels of inspections conducted by the US FDA, which results in long timelines for market approval.“The Indian government may recommend conducting different inspections together to avoid inefficient timelines. Based on the recent discussion with stakeholders, we understand that a full-fledged mutual recognition agreement (MRA) is highly unlikely to be agreed upon with the United States (US), given the vastly differing standards of GMP being followed in India.

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Lupin launches Luforbec 100/6 to treat adult asthma and COPD in Germany

Hormosan Pharma GmbH (Hormosan), Lupin’s wholly-owned subsidiary in Germany, announced the launch of Luforbec 100/6 (beclometasone 100 µg/formoterol 6 µg), a fix combination in a pressurized metered dose inhaler (pMDI) for the treatment of adult asthma and chronic obstructive pulmonary disease (COPD) in Germany. Luforbec 100µg/6µg pMDI is indicated for adult asthma and COPD treatment, where the use of an inhaled corticosteroid and long-acting beta2-agonist (ICS/LABA) is suitable. With the same active ingredients as Foster 100/6 pMDI and an extra fine formulation, Luforbec offers the same licensed indications and similar device characteristics.

LUPIN

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Zeon Lifesciences launches liquid-filled capsules to enhance bioavailability and absorption rates

Zeon Lifesciences, the global leader in the manufacturing of nutraceutical and herbal products, has launched the liquid-filled capsules. This according to the company is one-of-its-kind of capsules offering and unique delivery system enclosing a host of advantages including enhanced bioavailability and absorption rates. It also ensures precise and consistent dosages empowering individuals to have better control over the administration of Zeon's products. Realising the soaring demand for more convenient and practical dosage forms, Zeon has partnered with Collaborative Third-Party Manufacturing for Innovative Liquid Filled Capsules.

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