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The Veeda Newsletter

NOVEMBER 2022: ISSUE 11

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Indian Pharma Market Registers 7.2 Percent Growth In October

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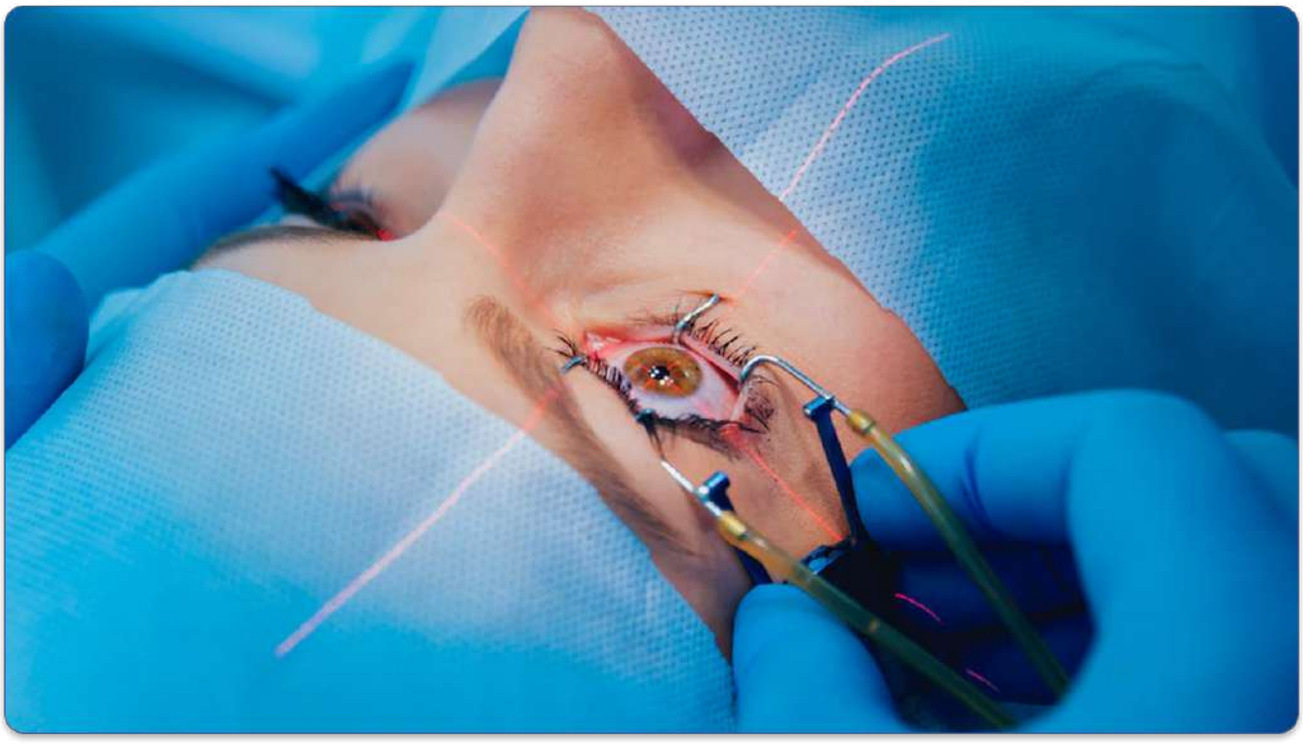
Our latest case study on the Bioequivalence of Brinzolamide & Brimonidine



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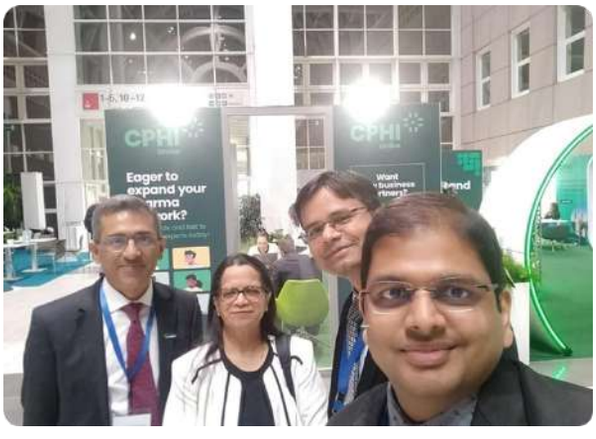
Here is a glimpse of our team at CPHI Frankfurt



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FDA approves most expensive drug yet at $3.5 million per dose

The FDA has just approved the most expensive drug on the market to date. The drug, known as Hemgenix, costs $3.5 million per dose and is administered to patients with the rare disorder Hemophilia B.Hemophilia B is the rarer form of the blood clotting disorder resulting from insufficient amounts of a protein called Protein IX. Most patients with hemophilia B are men and about 1 in every 40,000 people has the disorder. Women are often carriers, displaying no symptoms but passing the disorder on to their children.Small cuts or bruises can be life-threatening, and many people need treatments once or more a week to prevent serious bleeding.

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Quadripartite launches a new platform to tackle antimicrobial resistance threat to human and animal health and ecosystems

The Antimicrobial Resistance Multi-Stakeholder Partnership Platform was launched today to ensure the growing threats and impacts of antimicrobial resistance are addressed globally.The Food and Agriculture Organization of the United Nations (FAO), the UN Environment Programme (UNEP), the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH), known as the Quadripartite are joining forces on this initiative to underscore the threat AMR presents to humans, animals, plants, ecosystems and livelihoods.

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FDA Spurs Innovation for Human Food from Animal Cell Culture Technology

The world is experiencing a food revolution and the U.S. Food and Drug Administration is committed to supporting innovation in the food supply. As an example of that commitment, today we are announcing that we have completed our first pre-market consultation of a human food made from cultured animal cells. The agency evaluated the information submitted by UPSIDE Foods as part of a pre-market consultation for their food made from cultured chicken cells and has no further questions at this time about the firm's safety conclusion.

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WHO issues consolidated guide to running effective telemedicine services

The COVID-19 pandemic shone a spotlight on how telemedicine can help to deliver healthcare to all, especially for people living in remote areas and underserved communities. Countries around the world have struggled, however, to ensure routine use and long-term sustainable access to telemedicine services – even in those with the most robust health systems.In order to ensure the sustainable use of telemedicine beyond the COVID-19 pandemic and amongst multiple complex global health challenges, from conflict and disease outbreaks to climate change, WHO has released a new resource to help guide policy-makers, decision makers, and implementers in designing and overseeing telemedicine implementations.

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WHO releases first data on global vaccine market since COVID-19

WHO's Global Vaccine Market Report 2022, shows that inequitable distribution is not unique to COVID-19 vaccines, with poorer countries consistently struggling to access vaccines that are in-demand by wealthier countries.Limited vaccine supply and unequal distribution drive global disparities. The human papillomavirus (HPV) vaccine against cervical cancer has only been introduced in 41% of low-income countries, even though they represent much of the disease burden, compared to 83% of high-income countries.Affordability is also an obstacle to vaccine access

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No bar on taking corrective measures if some inconsistency or error in fixing retail price of drugs occurs: NPPA

The National Pharmaceutical Pricing Authority (NPPA), the drug price watchdog of the country, has said that there can be no bar on it to take corrective measures if it finds out some inconsistency or errors occurred while fixing the retail price of drugs and the Drugs Price Control Order (DPCO) also does not bar it from the same.It was taking a corrective measure related to the retail price notified for a vitamin product manufactured by Ravenbhel Healthcare and marketed by Mankind Prime Labs, after it had identified an error in the database based on which the price was fixed.

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Indian Medicines Pharmaceutical pays ₹10 cr dividend to Centre, Uttarakhand

State-owned Indian Medicines Pharmaceutical Corporation has paid a dividend of ₹10.13 crore to its stakeholders–Ministry of Ayush and the Uttarakhand government, the company said.A dividend of ₹9.93 crore was handed over to Ayush minister Sarbananda Sonowal.The company manufactures 656 classical ayurvedic, 332 unani and 71 proprietary ayurvedic medicines for various diseases. It supplies ayurveda and unani medicines to all states under National Ayush Mission (NAM) and 6,000 centres of Jan Aushadhi Kendras.

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Pharma exports to US, Europe and Middle East show growth in first six months of the fiscal

Exports of pharmaceutical products to the United States and others under the North America Free Trade Agreement (NAFTA), one of the largest export destinations for the country, has registered a growth of close to nine per cent in the first six months of the fiscal year 2022-23. Pharma exports to Europe have also shown a significant growth of 15.85 per cent during the first half of the fiscal.Exports to WANA (West Asia & North Africa) region, comprising of 19 countries in the Middle East including Bahrain, Kuwait, Oman, Qatar, Iraq, UAE, Saudi Arabia, Egypt, Sudan, Algeria, Morocco, Tunisia, Syria, Jordan, Israel, Lebanon, Yemen, Libya and South Sudan, has shown the highest growth at 16.83 per cent during the period, according to the data from the Central government.

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NPPA panel recommends retail price fixation for atorvastatin and bempedoic acid combo

The expert panel of National Pharmaceutical Pricing Authority (NPPA) has recommended retail price fixation for lipid lowering combination drugs comprising atorvastatin and bempedoic acid for Zydus Healthcare and Sun Pharma Laboratories.The Multi Disciplinary Committee (MDC) of experts in a recent meeting opined that the claim by Zydus Healthcare that the therapeutic use of the formulation is “for short term treatment of moderate pain” is not correct. Cardiovascular medicines are stated in size of packs and the therapeutic category of the formulation is like a lowering agent.

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Sun Pharma consolidated net up by 8.2% to Rs. 2,260 crore in Q2

Sun Pharmaceutical and Industries, a leading pharma company in India, has posted satisfactory financial performance during the second quarter ended September 2022 on account of higher sales in US and emerging markets. Its consolidated revenue increased by 13.1 per cent to Rs. 10,809 crore from Rs. 9,557 crore in the corresponding period of last year. Its net profit went up by 8.2 per cent to Rs. 2,260 crore from Rs 2,089 crore. EPS worked out to Rs 9.4 as against Rs 8.5 in the last period.

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CLINICAL RESEARCH

DBT to develop cost effective genome-editing based therapeutics for diseases having high burden

The Department of Biotechnology (DBT) has called for Letters of Intent (LoI) for research and development (R&D) projects to generate proof-of-concept for development of cost-effective genome editing-based therapeutics for targeted therapy for diseases having high burden in the country.The various approaches the eligible scientists or institutions can focus upon through the programme include genome editing based on the tool CRISPR-Cas for disease modelling to understand the etiology of various diseases and to delineate molecular mechanisms that can be exploited for development of cost-effective therapeutics; peptide nucleic acids-based genome editing approaches for treatment of various diseases having genetic basis; and genome editing-based therapeutics for various forms of cancer, cardiovascular disease, metabolic disorders, and neurodegenerative diseases.

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BeST to spur innovation in pharma & biotech sectors, to enable collaboration for entire R&D ecosystem

The Bengaluru Science & Technology Cluster (BeST), assisted by the Union government, is now positioned to accelerate innovation in pharma and biotech sectors and will enable collaboration for entire R&D ecosystem. The Science & Technology (S&T) Clusters are being established as formal umbrella structures for S&T organizations in various cities to have better synergy while retaining their autonomy. The earlier S&T clusters under this programme have been set up in Pune, Jodhpur, Delhi-NCR, Bhubaneshwar and Hyderabad

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Hirotsu Bio Science announces commercialization of ‘N-NOSE plus Pancreas’; world's first test to detect early-stage pancreatic cancer

Hirotsu Bio Science Inc has announced the commercialization of "N-NOSE plus Pancreas," the first next-generation cancer type specific test for the "N-NOSE". The "N-NOSE plus Pancreas" is the world's first test that can detect early-stage pancreatic cancer. Through the “N-NOSE plus Pancreas”, Hirotsu Bio Science aims to achieve early detection of as many cases of pancreatic cancer as possible and contribute to improving pancreatic cancer treatment results.Pancreatic cancer, which is particularly difficult to detect in its early stages and is often found in advanced stages up to stage 4, is responsible for about 30,000 deaths annually according to the latest cancer statistics, and the 5 years survival rate by cancer type is significantly lower than that of other cancers.

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World-first clinical trial in Perth could lead to breakthrough treatment for children with sarcoma

At 17 years of age, Angus Hollington was faced with the sudden need to have his leg amputated after enduring six years of invasive cancer treatment. "It wasn't a massive shock," he said."I just thought, 'Do whatever — fight the cancer more than anything.'"The Perth teenager was diagnosed with Ewing sarcoma at 11 years of age, and while several years of chemotherapy would see him conquer that battle, he then developed a secondary cancer which required his leg to be amputated.

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How Voice Response Technology Can Aid Clinical Trials

Clinical trials are the FDA-mandated process by which pharmaceutical companies confirm that the efficacy and safety of their new drugs make them worthy of government approval, then distribution to the public through the healthcare system.One of the major “hidden costs” of this laborious, time-consuming, and expensive drug development process is patient recruitment for these clinical trials, which accounts for nearly $2 billion on top of the nearly $3 billion spent on drug research.

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Merck expands haematology portfolio with acquisition of Imago for $1.35bn

Merck announced on November 21 that the company has agreed to acquire Imago Biosciences, a clinical-stage biotech developing the lysine-specific demethylase 1 (LSD1) inhibitor bomedemstat for the treatment of myelofibrosis (MF). Bomedemstat has several regulatory perks which makes it an attractive acquisition target, such as FDA fast-track and orphan drug designation. Merck will pay $36 per share in cash, totaling to $1.35 billion in equity, and thereby broaden the company's hematology portfolio by providing an opportunity to enter the burgeoning MF market.

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Telix Acquires Optimal Tracers

Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that it has entered into an agreement with Sacramento-based Northern California PET Imaging Center (NCPIC) to acquire Optimal Tracers, a radiochemistry development business providing radiochemistry process development services and research tracers for use in clinical trials.The acquisition of Optimal Tracers will bolster Telix's in-house radiochemistry development capability, by adding a highly skilled team to Telix and establishing a U.S.-based laboratory and production footprint for clinical trial doses.

Telix

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Bayer acquires German biotech start-up Targenomix

Bayer announced the acquisition of German biotech start-up Targenomix. The spin-off of the Max Planck Institute for Molecular Plant Physiology (MPI MPP) uses novel systems biology and computational life science tools to identify new modes of action for crop protection compounds.The Targenomix expertise, personnel, and platforms will be an important part of delivering on Bayer's commitment to the design of safe and effective molecules, and will accelerate the discovery and development of molecules with the potential to make agricultural production more sustainable despite dynamic challenges like climate change, and increasing weed, disease and insect resistance.

targenomix
the target identification company

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Fulgent Genetics acquires Fulgent Pharma for $100M

Fulgent Genetics on Monday announced that it has acquired Fulgent Pharma, a clinical-stage therapeutics development company, for approximately $100 million to be paid with a combination of cash on hand and shares of common stock.The firm separately reported that its third-quarter revenue was $105 million, a 54% decline from $227.9 million in Q3 2021. Billable tests delivered in Q3 were 952,000, versus 2.2 million in Q3 2021.

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Marksans acquires capacity from Tevapharm India

Marksans Pharma entered into a Business Transfer Agreement with Tevapharm India yesterday, to acquire its business relating to the manufacture and supply of bulk pharma formulations in Goa, as a going concern on a slump sale basis, a statement from Marksans Pharma has notified.The statement said that the transaction is in cash consideration, and is expected to be finalised by 1st April, 2023, subject to the usual closing conditions. Marksans has agreed to retain the site employees with the existing terms of employment.

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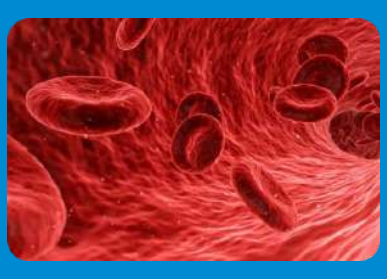
Metropolis Healthcare releases a study on anaemia

Metropolis Healthcare Limited, India's leading diagnostic service provider releases an all-India study on anaemia, aiding the efforts of Government of India's Anaemia Mukt Bharat (AMB) programme.The five-year study spanning January 2018 to July 2022 that included the testing of over 4,25,444 samples for adequacy of iron in patients' blood samples. Over 22.7% of the total sample size had iron deficiency. Around 50% of children in the age group of 0-12 years were found to be iron-deficient.



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Indian Pharma Market Registers 7.2 Percent Growth In October

The Indian Pharmaceutical Market (IPM) has registered a decline in growth for the month of October as industry sales rose only 7.2 percent at Rs 15338 crore in October, as per the data from market research firm All India Organization of Chemists and Druggists (AIOCD-AWACS).The industry sales rose as 7.2 percent (in terms of Value) at Rs 15338 crore in October compared to the same month in 2021. That compares with a 5.5 percent year-on-year increase in October 2021 and 13% growth in September 2022.

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Ophthalmologists see treatment for vision loss in diabetic retinopathy as major challenge with no drugs & late diagnosis

Ophthalmologists see treatment of vision loss in diabetic retinopathy as major challenge with no drugs and late diagnosis. Diabetic retinopathy is the leading cause of blindness among adults worldwide, including in developing countries such as India.Burden of diabetes-related blindness is undeniably posing a massive threat. Approximately one-third of people with diabetes develop some degree of the condition and it has become the leading cause of vision loss and blindness in adults. The condition can be broadly classified as non-proliferative and proliferative Retinopathy.

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Karnataka govt scouts for anchor investors for pharma sector

The Karnataka government is scouting for anchor investors in the pharma sector. This has been the key reason for pharma industry not finding any mention at the ongoing Global Investors Meet where the focus is on new-age industries like green hydrogen, electronics manufacturing, renewables, aerospace and defence, e-mobility, and infrastructure. The state government has set a target of attracting Rs. 5 lakh crore of investments and to generate 5 lakh jobs across sectors including pharmaceuticals.

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Ayurveda now recognised as a traditional medicine in more than 30 countries

Ayurveda is currently recognised as a traditional medicine in more than 30 countries and its acceptance is fast increasing globally, said Dr Munjpara Mahendrabhai Kalubhai, Minister of State of Ayush.Speaking at the Ayurveda Day 2022 programme in New Delhi held recently, he said, "Ayush, herbal products and medicines are exported to more than 100 countries. To boost the products and services in the field of Ayush, export promotion council which will cater to exports globally. As per the Research and Information System Centre for Developing Countries report, the current turnover of Indian Ayush industry is USD 18.1 billion and the market size has grown by 17 per cent between 2014 and 2020."

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