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AUGUST 2022: ISSUE 08

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Watch our Latest Webinar on Abatacept Biosimilar Clinical Assays today

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CBI files charge sheet in Biocon case

A senior official of the Central Drugs Standard Control Organisation(CDSCO) and a Biocon Biologics executive were arrested in June this year in an alleged bribery case The CBI has filed a charge sheet in an alleged bribery case in which a senior official of the Central Drugs Standard Control Organisation(CDSCO) and a Biocon Biologics executive were arrested in June this year, officials said. It is alleged that the bribe payment of ₹9 lakh to Joint Drug Controller S. Eswara Reddy was cleared by the associate vice president of Biocon Biologics L. Praveen Kumar, they said.

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FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

The U.S. Food and Drug Administration issued a final rule to improve access to hearing aids which may in turn lower costs for millions of Americans. This action establishes a new category of over-the-counter (OTC) hearing aids, enabling consumers with perceived mild to moderate hearing impairment to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription or a fitting adjustment by an audiologist.

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Almost 4% of the drug samples tested turned out to be not of standard quality in July

The Central Drugs Standard Control Organisation (CDSCO) has declared 53 samples of drugs it has tested as not of standard quality and one sample as misbranded during the month of July, 2022. The samples tested not of standard quality include batches from Cadila Pharmaceuticals, Morepen Laboratories, Ajanta Pharma Ltd, among others. The drug regulator has tested a total of 1,337 samples during the month of July and declared 53 out of them as not of standard quality. While one sample was declared as misbranded, there were no spurious drugs among the samples, according to data released by the CDSCO.

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New global alliance launched to end AIDS in children by 2030

Globally, only half (52%) of children living with HIV are on life-saving treatment, far behind adults where three quarters (76%) are receiving antiretrovirals, according to the data that has just been released in the UNAIDS Global AIDS Update 2022. Concerned by the stalling of progress for children, and the widening gap between children and adults, UNAIDS, UNICEF, WHO and partners have brought together a global alliance to ensure that no child living with HIV is denied treatment by the end of the decade and to prevent new infant HIV infections. The new Global Alliance for Ending AIDS in Children by 2030 was announced by leading figures at the International AIDS Conference taking place in Montreal, Canada.

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Allergan Aesthetics launches Juvéderm VOLUX in India

Allergan Healthcare India Private Limited, Bangalore announced on Saturday that it has launched Juvéderm VOLUX in India under its Business Unit of Allergan Aesthetics. According to the company's press statement, Allergan Aesthetics has obtained all the necessary approvals from the Central Drugs Standards Control Organization (CDSCO) office before launching this product in India. Juvéderm VOLUX is a combination of Hyaluronic acid 25 mg + Lidocaine hydrochloride 3 mg and is an injectable implant intended to restore and create volume of the face.

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NPPA fixes retail price of 45 formulations

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail price of 45 formulations under the Drugs (Prices Control) Order, 2013, based on the decision of the 100th Authority meeting held this month. The list of drugs which has prices fixed include various strengths of anti-diabetes drug sitagliptin combination, which went off patent recently and has seen several generic players jumping in to the market. Almost 25 out of the 45 drugs in the list are sitagliptin combinations, marketed by players including Torrent Pharmaceuticals, Micro Labs, Primus Remedies, Alembic Pharmaceuticals, Intas Pharmaceuticals, Cipla Ltd, and J B Chemicals and Pharmaceuticals.

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NPPA panel rejects Intas' application for exemption from provisions of DPCO for clozapine ER capsules

The expert panel of National Pharmaceutical Pricing Authority (NPPA) has rejected an application by Intas Pharmaceuticals Ltd for exemption from the provisions of Drug Price Control Order (DPCO) 2013, for various strengths of its formulation clozapine extended release (ER) capsules. The company has approached the Authority seeking exemption from the provisions of DPCO 2013, under Para 32 (iii) for the formulations clozapine extended release capsules 12.5 mg/25 mg/50 mg/100 mg and 200 mg.

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NPPA reiterates its revised retail price notification for Mankind Pharma's respiratory disease drug

The National Pharmaceutical Pricing Authority (NPPA) has reiterated its stand on revising the retail price of the respiratory disease drug formoterol fumarate combination marketed by Mankind Pharma, stating that the authority cannot be prohibited from making any rectification in the notified retail price on account of an error occurred only due to nomenclature issue of the data. The reiteration comes after the Authority recalculated the price of formoterol fumarate 12 mcg + budesonide IP 400 mcg hard gelatin capsule manufactured by Biodeal Pharmaceuticals and marketed by Mankind Pharma Ltd, in its previous meeting on June 28, 2022.

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Panel asks DoP to allocate budgetary funds to develop common infrastructure facilities for medical devices industry

The Department Related Parliamentary Standing Committee (DRSC) on Chemicals and Fertilisers has recommended the Department of Pharmaceuticals (DoP) to consider allocation of budgetary funds to facilitate development of common infrastructure facilities for the medical devices industry in the states other than the four which are already receiving funding under the scheme for promotion of medical devices park.

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NPPA extends timeline for trade margin capping of five medical devices

The National Pharmaceutical Pricing Authority (NPPA) has notified its decision to extend the timeline for the trade margin capping of the five medical devices which are essential during the Covid-19 pandemic period till December 31, 2022. The Authority said that it will monitor the trade margin rationalisation and its implementation as per the provisions of the Drug (Prices Control) Order, 2013, subject to maintenance of trade margin stipulated under the initial notification issued on July 13, 2021.

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Clinical trials without humans – why computer simulations could make drugs a lot cheaper

Before a drug or medical device is approved for use in humans, it must undergo a clinical trial. Clinical trials ultimately aim to answer two simple questions: is the drug or device safe? And does it do what it's supposed to do? The downside to clinical trials is that they are complex, take years to complete and are extremely expensive. However, a recent development called "in silico clinical trials" (trials conducted using computer simulation) are beginning to show their potential for substantially speeding up trials and drastically reducing their costs. And drugs regulators are starting to pay attention.

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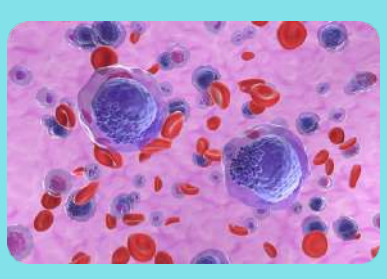
Oncolyze seeking investment for AML clinical trials

Oncolyze has launched a Regulation A+ funding campaign to spread awareness of OM-301 among cancer patients, healthcare professionals, and the investment community. Reg A is a type of offering that allows anyone to invest in Oncolyze and receive shares in the company. The investment opportunity is being hosted by SeedInvest and investments may be made in Oncolyze directly by visiting the SeedInvest website. Cancer is the second-leading cause of death globally, killing 10 million yearly worldwide. The estimated total annual economic impact of cancer is more than $1 trillion globally.



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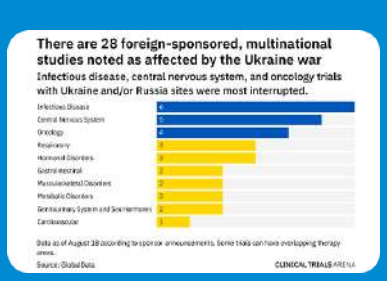
As Russia's clinical trials sector falls, Ukraine rebuilds

August 24 marks six months since the start of Russia's war in Ukraine. A United Nations update on August 15 reports that approximately 5,514 civilians have died and 7,698 people have been injured, with the actual figures likely to be considerably higher. The war is still doing huge damage to the economies of both countries due to the military invasion in Ukraine and companies pulling out of Russia. Focusing on the clinical trials landscape, as of August 18, 28 foreign-sponsored, multi-country studies were publicly acknowledged by sponsors as being impacted by the war, according to GlobalData's Clinical Trials Database.



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Pfizer discontinues development of dilated cardiomyopathy drug emprumapimod

Pfizer conducted an interim futility analysis of their global Phase III trial, REALM-DCM , to test the efficacy and safety of emprumapimod (PF-07265803) in patients with dilated cardiomyopathy (DCM) due to a lamin gene mutation. Based on this analysis, Pfizer found that the trial is unlikely to meet its primary endpoint, leading the company to cease the development of emprumapimod. According to GlobalData's Cardiomyopathy Report and Sales Forecast to 2031, the cardiomyopathies market was expected to grow from $1.6bn to $5.2bn across the US, 5EU (five major European markets: France, Germany, Italy, Spain and the UK) and Japan from 2021 to 2031.

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Sanofi to discontinue amcenestrant clinical development programme

Sanofi is discontinuing the global clinical development programme of amcenestrant, an investigational oral selective estrogen receptor degrader (SERD). The decision is based on the outcome of a prespecified interim analysis of the phase 3 AMEERA-5 trial evaluating amcenestrant in combination with palbociclib compared with letrozole in combination with palbociclib in patients with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer.

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Love Pharma Announces Strategic Acquisition of Doc Hygiene Pharmaceuticals Inc

Love Pharma Inc is pleased to announce that it has entered into a definitive agreement (the "Agreement") to acquire Doc Hygiene Pharmaceuticals Inc. ("Doc Hygiene") for aggregate consideration of US$300,000 (the "Acquisition"). Doc Hygiene has a premium hygiene product line and brand for hygiene and sanitizing needs and a robust e-commerce platform for products and SKU's "We are thrilled to announce the acquisition of Doc Hygiene," said Zach Stadnyk, CEO of LOVE.

LOVE PHARMA

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UPS acquires multi-national healthcare logistics company Bomi

UPS has announced plans to acquire Bomi Group, a multi-national healthcare logistics provider. The acquisition adds temperature-controlled facilities in 14 countries in Latin America and Europe. “As a leading global healthcare logistics company, Bomi enhances our portfolio of services and accelerates our journey to become the number one provider of complex healthcare logistics,” said Kate Gutmann, executive vice president and president of UPS International, Healthcare and Supply Chain Solutions

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Big Pharma deal-making primed for acceleration

After a prolonged period of scepticism towards major moves in the mergers and acquisitions (M&A) market, leading biopharmaceutical multinationals are returning to big deal-making. The M&A data for the second quarter of 2022 shows that while both the number of pharma deals signed and their overall value are still low compared to 2021, there are signs of a revival. Compared to the first quarter of the year, deal value was up 126 percent in the three months ending in June 2022, with 78 percent more deals struck.

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Amgen Will Acquire Chemocentryx in $4 Billion Deal

Amgen announced a definitive agreement to acquire ChemoCentryx, a biopharmaceutical company specializing in therapeutics to treat autoimmune diseases, inflammatory disorders, and cancer, for $52 per share in cash, which represents an enterprise value of approximately $3.7 billion. Each company’s board of directors has approved the transaction, which is expected to close in the fourth quarter of 2022.

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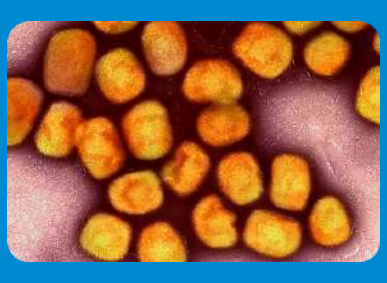
WeTrade enters partnership with Jiqing to sell monkeypox test kits and antigen tests

WeTrade Group Inc., an emerging growth company engaged in the business of providing software-as-a-services (SAAS) and cloud intelligent systems for micro-businesses, announced a strategic partnership with Jiqing Biomedical Technology Co. Ltd (Jiqing). The two companies plan to produce and provide exclusive sale channels for monkeypox virus test kits and antigen tests worldwide, aiming to develop domestic and international markets. This collaboration also means that WeTrade Group has started to cover the medical industry. Compared with the international advanced system, China's medical industry chain is relatively in the beginning stage, and most of the medical enterprises are small in scale and have limited competitiveness in the process of "operating globally".



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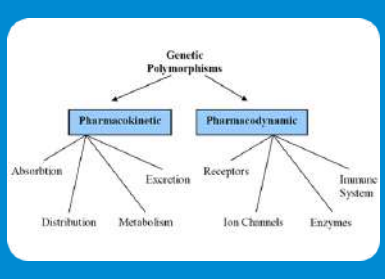
India works to strengthen itself in pharmacogenomics to stall drug reactions and propel precision medicine

India is now working to strengthen itself in pharmacogenomics to stall drug reactions and propel precision medicine. This is where pharmacogenomics gains importance as it is a scientific study of how a person's unique genetic makeup affects their response to drugs. According to Amol Naikawadi, Joint managing director, Indus Health Plus, even though modern drugs save millions of lives annually, yet one drug may not suit all. Drug reactions come about with several variables, including age, weight, diet, lifestyle habits, health conditions and genetic make-up. Precision medicine is fundamentally based on pharmacogenomics. It aims to provide healthcare that is individually tailored to each patient.



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DoP revises guidelines for PLI scheme for promotion of domestic medical devices

The Department of Pharmaceuticals (DoP) has revised the guidelines for the production linked incentive (PLI) scheme for promoting domestic manufacturing of medical devices, dividing the eligible products into two categories and allocating incentives separately for them. The revised guideline has an addition to the definition of applicant, under which the applicant applying for products listed in Annexure 1 of the guideline shall be referred to as Category A applicant and those applying for products in Annexure 1A shall be referred to as Category B. Changes are made in other clauses and Annexures based on this revision.

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"Baseless": Dolo 650 maker Micro Labs rejects allegations of Rs 1,000 crore worth freebies to doctors

Maker of Dolo 650, Micro Labs, has termed the allegations of Rs 1,000 crore worth of freebies to doctors as baseless. The pharma company said in a statement that in some of the recent media reports it has been falsely and maliciously alleged that the company has been distributing freebies worth Rs 1,000 crore to promote Dolo 650 in one year. The company clarified that the amount referred to pertains to the total sales and marketing expenses incurred by the company for its total India business in the last five years' period and spent across its whole portfolio.

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Kerala govt soon to constitute a statutory body for registration of certificate of B Pharm Ayurveda

The government of Kerala may soon find a solution to the problem of registration of certificate of the Ayurveda pharmacy graduates (B Pharm Ayurveda) with a statutory body in the state, according to the state association of the B Pharm Ayurveda graduates. Hundreds of graduates in Ayurveda pharmacy have been struggling for over ten years, in the absence of a registration council, to get their degree certificates registered with a statutory body

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R&D funding through BIRAC declines in three years

The amount released by the Central government towards drug development and research and development (R&D) through the Biotechnology Industry Research Assistance Council (BIRAC) has come down by almost 50 per cent in the last two fiscal years. The disbursement declined drastically in 2020-21, during when the Covid-19 pandemic hit the country and the government allocated more funds for vaccines and drugs to fight the pandemic, as compared to the year 2019-20. According to the data available from the ministry of chemicals and fertilisers, the BIRAC, the public sector undertaking of Department of Biotechnology (DBT), has disbursed Rs. 4.19 crore in the year 2021-22, as compared to Rs. 4.98 crore in 2020-21 and Rs. 8.26 crore in 2019-20. The total disbursement during these three years was around Rs. 17.43 crore.

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For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

Corporate Office

VEEDA CLINICAL RESEARCH LIMITED
Block 6, Magnet Corporate Park,
100 ft. Thaltej - Hebatpur Road,
Nr.Sola Bridge, Off. S.G.Highway,
Thaltej, Ahmedabad 380 054

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

OTHER ADDRESS:

- Sarkhej - Gandhinagar Highway
  Vedant Complex, S. G. Highway, nr. YMCA club,
  Ahmedabad, Gujarat 380051
- Insignia, Besides Auda Garden, Opp. Zenobia
  Residency, Sindhu Bhavan Road, Off. S. G. Highway,
  Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium
  Panchot Cir, Kunal, Mehsana, Gujarat 384002