

MD Ajay Tandon Explicates Veeda's Refreshed Vision & Mission



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Partners in Creating a healthier tomorrow



Veeda News

Latest Webinar on
Dermatology Study Design,
Regulatory Strategies, and
Patient Participation



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Dermatology: Study Design, Regulatory Strategies, and Patient Participation



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REGULATORY

Bacteria that Causes Rare Disease Melioidosis Discovered in U.S. Environmental Samples

The Centers for Disease Control and Prevention (CDC) has identified for the first time in domestic environmental samples the bacteria that causes a rare and serious disease called melioidosis. The bacteria, *Burkholderia pseudomallei* or *B. pseudomallei*, was identified through sampling of soil and water in the Gulf Coast region of Mississippi. It is unclear how long the bacteria has been in the environment and where else it might be found in the U.S.; however, modeling suggests that the environmental conditions found in the Gulf Coast states are conducive to the growth of *B. pseudomallei*.



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CDSCO issues alert on Baxter's blood purification device hemoperfusion cartridge

The Central Drugs Standard Control Organisation (CDSCO) has issued a medical devices alert on Baxter Healthcare's Absorba Hemoperfusion Cartridge 300 C and Absorba 300 C, devices used in blood purification, due to presence of particulate matter within the cartridge. Baxter has informed the CDSCO that it "is issuing an urgent medical device recall for the Adsorba Hemoperfusion Cartridge 300 C and Adsorba 300 C due to the presence of particulate matter within the cartridge".



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Reddy, held in bribery case, in shortlist for new DCGI

The government has short-listed five candidates to be the new Drug Controller General of India (DCGI), including S. Eswara Reddy, who is in judicial custody on corruption charges. The DCGI is meant to ensure only quality drugs and cosmetics are sold in the country, give approval for new drugs and regulate clinical trials. With the present regulator V. G. Somani's term set to end on 14 August, the Union Public Service Commission advertised the position back in February.



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Tough regulatory rules likely for sale of codeine-based cough syrups after MPs raise concerns

The government is reviewing the policy to ban manufacturing and sale of codeine-based cough syrups after several MPs raised concerns that they are being used as narcotic drugs than as medicine. Codeine is an opioid-based analgesic, mostly used to treat coughing, pain and diarrhoea, and it is one of the natural plant alkaloids found in extracts of opium. Based on the request by several politicians to health minister Mansukh Mandaviya to ban cough syrups, a copy of which was accessed by News18.com, the health ministry had asked the Drug Controller General of India (DCGI) in March to "conduct a review and submit recommendation".



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NTAGI's Standing Technical Sub-Committee recommends vaccines for kids below 12 years of age

The National Technical Advisory Group of Immunization's Standing Technical Sub-Committee (STSC) on Friday recommended the use of Biological E's Corbevax and Bharat Biotech's Covaxin for kids between 5-12 years, an official said. However, NTAGI has not taken any decision to include these vaccines under the national covid-19 vaccination programme. "The pediatric data of covid-19 vaccines—Corbevax and Covaxin were reviewed and analyzed in the STSC meeting held last month and it was decided to recommend the both the vaccines for children below 12 years," said the official adding that the matter will be taken up in the next meeting.



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FINANCIAL

Government gears up to form Drug Tribunal Board

The government is gearing up to set up a Drug Tribunal Board with an aim to decriminalize offences punishable under Drugs and Cosmetics Act. The decision to this effect was taken by Union minister of health and family welfare and chemicals and fertilizers Mansukh Mandaviya at a meeting convened by National Pharmaceutical Pricing Authority (NPPA) on July 26, 2022 to discuss trade margin rationalization. The government is keen to rationalize trade margins on non-scheduled drugs to reduce their prices



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NPPA fixed ceiling prices of 890 formulations and retail price of 2023 new drugs: Minister

The National Pharmaceutical Pricing Authority (NPPA) has so far fixed ceiling prices of 890 scheduled formulations and retail price of around 2,023 new drugs, among others, said minister of state for chemicals and fertilisers, Bhagwanth Khuba. In a written reply in Lok Sabha, he said that the NPPA has fixed the ceiling prices of 890 scheduled formulations across various therapeutic categories under the National List of Essential Medicines (NLEM) 2015 and retail prices of 2,023 new drugs under the Drug (Prices Control) Order, 2013.



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NPPA directs Neon Laboratories to continue manufacturing of Tropine injection for six more months

The National Pharmaceutical Pricing Authority (NPPA) has decided to further extend its direction to Mumbai-based Neon Laboratories to continue manufacturing scheduled formulation atropine injection 0.6 mg/ml, a drug to treat bradycardia or slow heart rate, for six more months. Neon Lab has earlier submitted Form IV seeking the drug price regulator's permission to discontinue the drug under the drug control order. The Authority, in a meeting held on June 28, deliberated upon the company's request and decided that Para 3 of Drugs (Prices Control) Order, 2013, be invoked in relation to Neon Laboratories Ltd for the scheduled formulation Tropine 1ml injection (atropine sulphate injection 0.6 mg/ml) for six more months, upto February 5, 2023.



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NPPA extends its mandate to Serum Institute to continue manufacturing of TT injection for six more months

The National Pharmaceutical Pricing Authority (NPPA) has extended its mandate to Pune-based Serum Institute of India (SII) to continue manufacturing two of its scheduled formulations against tetanus for another six months, till December 22, 2022. SII has earlier submitted Form IV intimation seeking the drug price regulator's approval to discontinue these two formulations. The Authority meeting held on June 28, observed that its earlier order under the provisions of the Drugs (Prices Control) Order, 2013, asking the company to continue production of these two formulations - tetanus toxoid injection in 0.5 ml pack and tetanus toxoid injection in 5 ml pack - was extended to six more months, till December, 2022. The mandate was earlier applicable till June 22, 2022.



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Cipla to invest Rs 26 cr in digital tech co GoApptiv to raise stake to 22%

Pharma company Cipla has agreed to acquire an additional stake for nearly Rs 26 crore in digital tech company GoApptiv Private to raise its shareholding to 22.02 per cent, the company said on Monday. The investment will be made in equity shares and Compulsorily Convertible Preference Shares and is likely to be completed within 30 days or such other date mutually agreed between the parties, Cipla said in a regulatory filing. Cipla's earlier investment in GoApptiv in June 2020 has yielded growth and expanded Cipla's channel reach across lower tier towns in India.



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CLINICAL RESEARCH

Immunocompromised adults at increased risk of severe Covid-19 outcomes

As Covid-19 infections have continued to rise in recent weeks, increasing hospital admissions combined with staff sickness are placing an increased strain on health systems around the world. Recent research published by the US Centres for Disease Control and Prevention (CDC) has shown that immunocompromised people face an increased risk of intensive care unit (ICU) admissions and death due to illness associated with Covid-19. It is important that we closely monitor transmission levels in immunocompromised groups to minimise severe illness and mortality.



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VistaGen's horizons may shrink after clinical trial setback

The drug – codenamed PH94B – was unable to alleviate SAD symptoms in adults asked to complete a public speaking challenge in the PALISADE-1 compared to placebo. The announcement of the result was swiftly followed by an 86% decline in VistaGen's share price, reflecting investor concerns about the potential of PH94B, which is in multiple trials across SAD indications and is the company's primary R&D programme. The company is now firmly in penny share territory at \$0.15, down from a 52-week high of more than \$3.25.



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Clinical trials could get monkeypox drug to desperate patients

On a sultry Tuesday evening in New York City, Luke Brown excitedly opened a newly delivered bottle of black-and-orange pills, popped his first dose in his mouth, and washed it down with root beer. Having contracted monkeypox this month, the lanky, bespectacled 29-year-old project manager had been suffering from what he called "the most severe pain of my life" for over a week before he finally was able to obtain a course of antivirals – a treatment he hoped would soon clear up his lesions and alleviate his suffering.



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NIH-funded clinical trial finds that a type of 'step therapy' is an effective strategy for diabetic eye disease

Clinical trial results from the DRCR Retina Network suggest that a specific step strategy, in which patients with diabetic macular edema start with a less expensive medicine and switch to a more expensive medicine if vision does not improve sufficiently, gives results similar to starting off with the higher-priced drug. The main complication of diabetic macular edema, fluid build-up in the retina that causes vision loss, is commonly treated with anti-vascular endothelial growth factor (VEGF) drugs. The trial was funded by the National Eye Institute (NEI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), both part of National Institutes of Health



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Moderna's mRNA vaccine for Nipah virus to go through Phase 1 Clinical trial

The National Institute of Allergy and Infectious Diseases (NIAID) which is a part of the National Institutes of Health (NIH) announced Wednesday that it has launched an early-stage clinical trial evaluating an investigational vaccine to prevent infection with the Nipah virus. Manufactured by Moderna, the experimental vaccine is was developed in collaboration with NIAID's Vaccine Research Center. According to reports, it is based on a messenger RNA (mRNA) platform—a technology used in several approved Covid-19 vaccines.



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MERGER AND ACQUISITION

Sirio Pharma to Acquire 80% Equity of Best Formulations

Sirio Pharma Co., Ltd., and contract manufacturer Best Formulations, Inc., have entered into an agreement for Sirio to acquire 80% equity of Best. Founded in 1984, Best Formulations, manufactures for leading health and wellness brands in the U.S. "This is a significant milestone in Sirio's strategy to establish a global manufacturing footprint," said Doug Brown, Managing Director of Sirio Americas, in an announcement posted to LinkedIn. "By adding Best's world-class North American manufacturing facilities to our established bases in Asia and Europe, the combined company will be able to better serve both our global and regional customers with local production everywhere they want to be."



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NewAmsterdam Pharma and Frazier Lifesciences Acquisition Merging in \$326M Deal

NewAmsterdam Pharma Holding B.V. and Frazier Lifesciences Acquisition today announced that they have entered into a definitive business combination agreement at an enterprise value of \$326 million. The announcement follows reporting last week that a deal was imminent. If approved, NewAmsterdam Pharma would list on the Nasdaq under the ticker symbol NAMS. New Amsterdam is a late clinical-stage company focused on the research and development of transformative oral therapies for major cardiometabolic diseases.



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ARS Pharmaceuticals to merge with Silverback Therapeutics

ARS Pharmaceuticals has signed a definitive agreement to merge with Silverback Therapeutics in an all-stock transaction. The combined company will operate under the name ARS Pharmaceuticals and be headquartered in San Diego, California, US, after the completion of the transaction. It will focus on the potential regulatory clearance and commercialisation of ARS' investigational epinephrine nasal spray, neffy. The needle-free, low-dose intranasal epinephrine nasal spray is currently under clinical development.



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BeiGene, InnoRNA enter strategic research collaboration to jointly discover novel mRNA therapies

BeiGene, a global, science-driven biotechnology company, announced it entered into a worldwide strategic collaboration with InnoRNA, a biotechnology company with expertise in LNP-based delivery technology and mRNA drug discovery, to leverage its innovative technology platform for developing mRNA-based therapeutics. "As a global biotechnology company, BeiGene is committed to delivering next-generation therapies through our own internal discovery engine and leveraging cutting-edge technology from experienced and innovative partners," said Lai Wang, Ph.D., global head of R&D at BeiGene. "This collaboration with InnoRNA advances and supports our research efforts in the important field of mRNA therapies while securing critical, proprietary delivery tools."



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AstraZeneca to acquire US biotech company TeneoTwo

AstraZeneca announced an agreement to acquire TeneoTwo, Inc., including its phase I clinical-stage CD19/CD3 T-cell engager, TNB-486, currently under evaluation in relapsed and refractory B-cell non-Hodgkin lymphoma. The acquisition of TNB-486 aims to accelerate the development of this potential new medicine for B-cell haematologic malignancies, including diffuse large B-cell lymphoma and follicular lymphoma. Building on the success of Calquence (acalabrutinib), TNB-486 further diversifies AstraZeneca's haematology pipeline that spans multiple therapeutic modalities and mechanisms to address a broad spectrum of blood cancers.



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INDIAN PHARMA

Kosmoderma Healthcare gears up to expand in Delhi & Chennai

Kosmoderma Healthcare Pvt Ltd., India's leading aesthetic dermatology and cosmetology brand, has laid the foundation to expand its presence in the country. The brand is all set to open new clinics in the capital city New Delhi, and the cultural and economic centre of South India, Chennai, where it already has an established presence. The global aesthetic medicine market is witnessing a compound annual growth rate of 9.2 per cent between 2020 and 2027, so there's a massive demand for beauty products and services among young citizens. Tapping into this high-potential market, Kosmoderma will inaugurate a first-of-its-kind clinic in Greater Kailash Delhi.



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ENTOD Pharma Launches Dermatological Venture In India

ENTOD Pharmaceuticals has recently launched its dermatological venture in India in collaboration with its UK sister concern ENTOD Beauty London Ltd. ENTOD Beauty London products will now be sold in India through Entod Pharmaceuticals nationwide sales field representative & distributor networks. The UK developed products will be manufactured in India under the Make in India Initiative and through a technology transfer arrangement between the two companies.



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Glenmark Pharma launches type-2 diabetes drug in India

The global pharmaceutical company said today announced the launch of sitagliptin and its fixed dose combinations (FDCs) for adults with Type-2 diabetes in India. The company has introduced 8 different combinations of sitagliptin based drugs under the brand name SITAZIT and its variants at affordable price. According to the International Diabetes Federation (IDF), the prevalence of diabetes in India is 8.3% with around 74 million adults living with diabetes as of 2022. Glenmark's SITAZIT and its variants will play an instrumental role in raising accessibility of sitagliptin to type-2 diabetic patients, which is considered as the gold standard molecule in DPP4 inhibitor therapy. It will help the patients to manage their glycemic level effectively and bring better compliance.



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Centre to roll out SPI schemes with focus on MSMEs and clusters

The ministry of chemicals and fertilisers is planning to roll out the initiatives under its schemes for Strengthening Pharmaceutical Industry (SPI) with focus on the micro, small and medium enterprises (MSMEs) and pharma clusters in the country in a programme on July 21, 2022. The initiatives would be formally unveiled by Union minister of chemicals & fertilizers and health & family welfare Dr. Mansukh Mandaviya, on July 21, 2022 at Dr. Bhimrao Ambedkar International Convention Centre. Minister of state for chemicals & fertilizers Bhagwanth Khuba shall also be gracing the occasion. Senior officials from department of chemicals & fertilizers, ministry of MSME, SIDBI, NSIC, banks besides representatives of industry, entrepreneurs, start ups etc.



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PETA India announces grant for promoting animal-free methods for toxicology testing

People for the Ethical Treatment of Animals (PETA) India, a leading animal rights organization, has announced a grant for advancing animal-free methods for toxicology testing in the country. Currently, toxicity testing is performed by exposing animals to very high doses of chemicals—often at levels 100 to 1,000 times higher than humans would typically be exposed to. This is usually done to help predict the chemical's possible effects on people or the environment, including the animals in it. Such studies result in a great deal of animal pain, suffering, distress and death. On the other hand, many drugs that appear safe and effective in animals fail in humans, or cause significant harm, and even death. There are reports stating that more than 80 HIV/AIDS vaccines successful in nonhuman primates failed in human trials.



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