The Veeda Newsletter

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Veeda Clinical Research limited integrates Biopharma Business Unit at Bangaluru, India

Partners in Creating

a healthier tomorrow

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VEEDA NEWS

Join us at BIO-Europe 2023 from November 6–8, 2023, in Munich, Germany

Meet our experts from Veeda Biopharma Division, a one-stop solution for all your biopharmaceutical development needs—Bridging Ideas to Impact, one Biopharmaceutical Breakthrough at a time.

Know More!

Join us at the 15th Annual Outsourcing in Clinical Trials New England 2023 from November 1st to 2nd, 2023

Meet our experts to learn more about Veeda's comprehensive end-to-end support throughout the clinical trial process, from Protocol Development, Site Monitoring & Management to Regulatory Compliance and Data Management.

Know More!

Tune in to our latest podcast on Building Trust in Clinical Trials

Gain deeper insights into our CTMS integration on streamlining study processes, elevating study efficiency, and enhancing overall research outcomes through the automation of patient visit tracking and protocol deviation detection.

Listen Now!

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Venus Remedies gets UK marketing authorization for bleomycin 15,000 IU

Venus Remedies has bagged the market authorization in the United Kingdom for bleomycin 15,000 IU powder for solution for injection/infusion by its German subsidiary, Venus Pharma GmbH. This milestone, according to the company not only expands the pharma giant's global presence but also underscores its commitment to advancing cancer care with innovative solutions. Bleomycin 15,000 IU is a potent medication that contains the active ingredient bleomycin sulfate. It belongs to a group of medicines known as cytostatic drugs, specifically designed to combat cancer. This class of medications, often referred to as chemotherapy, is renowned for its effectiveness in targeting cancer cells and preventing their uncontrolled division.

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DCGI calls upon Indian pharma cos to raise standards of manufacturing processes to global level

As India has obviously become the manufacturing hub of pharmaceuticals for the medicinal requirements of the world population, it is necessary for the Indian companies to raise the standards of manufacturing processes to the global level, observes Drug Controller General of India (DCGI), Dr. Rajivsingh Raghuvanshi.He said he is making this statement in the wake of concerns recently raised by regulators of foreign countries over the quality of Indian made pharmaceuticals. The drug regulator of India said the government received 18 international alerts in the last nine months, hence the government wanted to upgrade the good manufacturing practices (cGMP), the revision of which is in the offing.

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EMA takes further steps to address critical shortages of medicines in the EU

EMA published PDF icon details of the newly created solidarity mechanism developed by the EMA Medicines Shortages Steering Group (MSSG). This voluntary mechanism allows Member States to support each other in the face of a critical medicine shortage. The solidarity mechanism, which is based on an informal setup during COVID-19, will enable any Member State facing a critical shortage that has been escalated to the MSSG for coordination at European level to request assistance from other Member States in obtaining medicine stocks.

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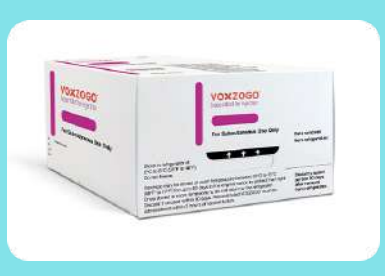
US FDA approves BioMarin's Voxzogo for children of all ages with achondroplasia

BioMarin Pharmaceutical Inc., a global biotechnology company dedicated to transforming lives through genetic discovery, announced that the US Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for Voxzogo (vosoritide) to increase linear growth in pediatric patients with achondroplasia with open epiphyses (growth plates). This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Previously, Voxzogo was indicated for children who were 5 years of age and older. This expanded indication now includes children of all ages with open growth plates.



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CDSCO declares over 5% of drug samples tested in September as NSQs

The Central Drugs Standard Control Organisation (CDSCO) has declared almost 5.2 per cent of the total drug samples it has tested during the month of September, 2023 as Not of Standard Quality (NSQ). This includes samples labelled as manufactured by Mankind Pharma, Bharat Biotech International and public sector undertakings (PSUs) Hindustan Antibiotics Ltd and Karnataka Antibiotics and Pharmaceuticals Ltd.According to the list of NSQs released by the drug regulator for the month of September, 62 were declared as NSQs out of a total number of 1,188 samples tested during the month. Out of the total, 1,126 samples were declared as of standard quality.

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NPPA approves change of manufacturer for brands from Torrent Pharma and Sun Pharma in line with guideline

The National Pharmaceutical Pricing Authority (NPPA) has approved applications from Torrent Pharma and Sun Pharma Laboratories to shift manufacturing to their own facilities at the existing retail price.The decision comes after the Authority in its earlier meetings framed guidelines for examining such cases and allowing the change of manufacturer for formulations for which retail prices has been fixed already.In a latest meeting, the Authority noted the changes proposed by the marketers to manufacture the brands on their own. This include Torrent Pharmaceuticals' applications for manufacturing of diabetes formulations of Azulix 3MF and 4 MF, cardiology drugs Unistar Gold 20 and Rozuplatt capsules.

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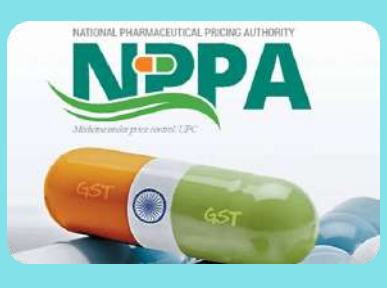
NPPA to revise ceiling prices of certain formulations to rectify anomaly in calculating revised prices

The National Pharmaceutical Pricing Authority (NPPA) has decided to revise the ceiling prices of certain formulations notified on March 31, 2023 in order to rectify an anomaly that took place while calculating the revised prices based on the Wholesale Price Index (WPI) increase of 12.1218 per cent.The Authority has revised the ceiling prices of scheduled formulations based on the WPI for the year 2023 through various notifications on March 31, 2023.However, some of the companies approached the Department of Pharmaceuticals (DoP) with review applications stating that while revising the ceiling prices in these notifications, the ceiling price for all formulations has been incorrectly rounded down by the Authority rather than to the nearest zero.



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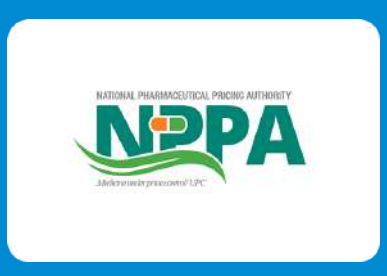
NPPA releases draft ceiling price calculation sheet with significant price cut for a brain cancer drug

The National Pharmaceutical Pricing Authority (NPPA) has issued the draft ceiling price calculation for 10 formulations including significant reduction in prices of a brain cancer drug formulation to almost 70 per cent.The pricing authority in the 17th lot of draft version of calculation of ceiling price, as part of revising the ceiling prices based on the revised Schedule I of the Drugs (Prices Control) Order, 2013, suggested a 69.15 per cent price cut for temozolomide tablet 100 mg to Rs. 594.10 per unit as compared to the current ceiling price of Rs. 1,925.47 per tablet.



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NPPA clarifies orthopaedic knee implant manufacturers & importers can raise 10% of MRP

The National Pharmaceutical Pricing Authority (NPPA) has clarified that the manufacturers and importers of orthopedic knee implants can avail an increase of 10 per cent in maximum retail price (MRP) with effect from September 16, 2023 for the preceding 12 months.The clarification is on a notification by the Authority on September 15, 2023 extending the ceiling price fixed for orthopedic knee implants for knee replacement system for one more year from September 16, 2023 till September 15, 2024.Following the notification, various stakeholders approached the Authority for clarity regarding increase in price for these products.

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We expect mid-teen growth for full year despite softening of US biotech segment: Jonathan Hunt, SyngeneLink:

If you step back out of that U.S. biotech segment, look at the rest of the business, big pharma, big biotech, or whether or not you look in Europe and Asia, those markets seem to be pretty much insulated and unaffected by that," says Jonathan Hunt, MD & CEO, Syngene.

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New data for Arexvy, GSK's RSV vaccine, show potential to help protect adults aged 50 to 59 at increased risk for RSV disease

GSK plc announced positive preliminary results from its phase III trial [NCT05590403] evaluating the immune response and safety of Arexvy (respiratory syncytial virus vaccine, adjuvanted) in adults aged 50 to 59, including those at increased risk of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) due to certain underlying medical conditions. These results were presented at the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) meeting on 25 October 2023. This vaccine is currently approved in the US for active immunisation for the prevention of RSV-LRTD in adults 60 years of age and older. It is also approved in Europe, Japan and several other countries.

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Ceremorphic opens new Life Sciences Division with new design methods based on proprietary analog and AI to reduce R&D costs

Ceremorphic, a fabless silicon and system development company, has formed a new life sciences division called Ceremorphic Life Sciences, which has been established to transform the entire drug discovery and development process. The new division will have access to Ceremorphic's own proprietary analog and AI technology platform that will allow its team of biology and chemistry experts to begin developing drugs at a pace unprecedented in the pharmaceutical industry. With more than 10,000 diseases in the world and only 500 drugs available today, the Ceremorphic Life Sciences platform is the first solution capable of closing that gap by bringing efficiency at each level of the current design pipeline. Recent innovations on novel algorithms

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Chugai's Alecensa reduces the risk of disease recurrence or death by 76% in people with ALK-positive early-stage NSCLC

Chugai Pharmaceutical Co., Ltd. announced results from the primary analysis of the phase III ALINA study of anti-cancer agent/ALK inhibitor Alecensa (alectinib), demonstrating a statistically significant and clinically meaningful improvement in disease-free survival (DFS; primary endpoint).The study results showed that Alecensa reduces the risk of disease recurrence or death by 76% (hazard ratio [HR]=0.24, 95% CI: 0.13-0.43, p<0.0001) compared with platinum-based chemotherapy in people with completely resected stage IB (tumour =4cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). A clinically meaningful improvement of central nervous system (CNS)-DFS was also observed (HR=0.22; 95% CI: 0.08-0.58).

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Gilead Sciences announces new clinical trial in Europe to assess lenacapavir for HIV prevention

Gilead Sciences, Inc. announced PURPOSE 5, the first phase 2 clinical trial to evaluate an investigational long-acting HIV prevention option in Europe. The study will assess the persistence—defined as consistent and continuous use—of lenacapavir compared with emtricitabine/tenofovir disoproxil fumarate (F/TDF) in people who may benefit from pre-exposure prophylaxis (PrEP) and who are not currently taking PrEP. The study has an intentional focus on recruiting participants from groups across France and the United Kingdom that are disproportionally affected by HIV and often underrepresented in clinical trials.

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PharmaKure reports positive results for novel blood test to identify biomarkers in patients with Alzheimer's disease

PharmaKure, a pharmaceutical company spun out from the University of Manchester, announces successful study results for a novel whole blood test for quantifying Alzheimer's disease biomarkers. PharmaKure's proprietary ALZmetrix blood test can identify blood-based biomarkers in patients with Alzheimer's disease to provide early warning of cognitive decline.The study was designed to focus on the testing of whole blood. A number of biomarkers were accessed for the stratification of Alzheimer's subjects who had previously been tested for amyloid deposits, using either brain PET imaging or cerebrospinal fluid (CSF).

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Basilea acquires novel clinical-stage antifungal to treat Aspergillus mold infections from

Basilea Pharmaceutica Ltd, a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced that it has entered into an asset purchase agreement with privately owned Gravitas Therapeutics Inc. for GR-2397, a clinical-stage antifungal compound with a novel mechanism of action, targeting invasive mold infections caused by Aspergillus species.David Veitch, chief executive officer of Basilea, stated: “This is the first transaction in the implementation of our strategy to expand our clinical-stage anti-infectives pipeline and to complement our portfolio of marketed products, Cresemba and Zevtera. We are looking forward to developing this asset.”

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RespireRx Pharmaceuticals’ arm ResolutionRx inks agreement with Ab Initio for manufacturing of dronabinol

RespireRx (formerly known as Cortex Pharmaceuticals, Inc.) Pharmaceuticals Inc., focused on the discovery and development of innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling, and ResolutionRx Ltd, an unlisted public Australian company, and a subsidiary of RespireRx, jointly announce that on October 9, 2023, ResolutionRx entered into a Master Services Agreement (“MSA”) with Ab Initio Pharma Pty Ltd, (Ab Initio) an Australian company under which Ab Initio will manufacture, formulate, test and supply ResolutionRx with therapeutic drugs based on lipid nanoparticle technology licensed from RespireRx.

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Bristol Myers Squibb to buy Mirati Therapeutics in deal worth up to $5.8 billion

On 8th October Bristol Myers Squibb announced it will acquire drug maker Mirati Therapeutics in a deal worth up to $5.8 billion, diversifying its oncology business and adding drugs it hopes can help offset expected lost revenue from patent expirations later this decade. Bristol Myers Squibb will pay $58 per share in cash. As part of the deal, Mirati Therapeutics stockholders will also get one non-tradeable contingency value for each Mirati share held, potentially worth $12 per share in cash while representing an additional $1 billion of value opportunity, according to a company statement.

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Amgen completes acquisition of Horizon Therapeutics for $27.8 billion

Amgen Inc announced that it has completed its acquisition of Horizon Therapeutics plc for $116.50 per share in cash, representing a transaction equity value of approximately $27.8 billion after fending off a legal challenge by the US antitrust watchdog.Today marks an exciting milestone as the company welcomes Horizon Therapeutics employees to Amgen and begin working together to serve even more patients around the world suffering from serious illnesses, a company statement says. The company has strong momentum in core business and the addition of Horizon will further position Amgen as a leader across a broader range of diseases.

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Lilly to buy radiopharma company, POINT Biopharma for $1.4 billion

Eli Lilly and Company and POINT Biopharma Global, Inc. announced a definitive agreement for Lilly to acquire POINT, a radiopharmaceutical company with a pipeline of clinical and preclinical-stage radioligand therapies in development for the treatment of cancer. Radioligand therapy can enable the precise targeting of cancer by linking a radioisotope to a targeting molecule that delivers radiation directly to cancer cells, enabling significant anti-tumour efficacy while limiting the impact to healthy tissue.

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DoP modifies operational guidelines for PLI scheme for pharmaceuticals

The Department of Pharmaceuticals (DoP) has released modifications in the operational guidelines for production linked incentive (PLI) scheme for pharmaceuticals elaborating the conditions for annual incentive allocations, clarifying timeline for periodic claims and procedures in case of change in the applicant group structure, among others.According to the fresh modifications related to the calculation of incentive in the operational guidelines, the annual incentive allocation to each applicant shall be based on conditions including that it is mandatory to the applicant company to avail incentive by achieving eligible sales in the fifth and sixth year under the scheme.

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Granules India receives US FDA approval for generic Nexium delayed-release capsules

Granules India Limited announced that the US Food & Drug Administration (FDA) has approved its Abbreviated New Drug Application (ANDA) for esomeprazole magnesium delayed-release capsules USP, 20 mg and 40 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Nexium delayed-release capsules, 20 mg and 40 mg, of AstraZeneca Pharmaceuticals LP. Esomeprazole magnesium capsules are indicated for short-term treatment of heartburn and other symptoms associated GERD, risk reduction of nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcer in adults

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Indian pharma companies still considering expansion into phytopharmaceuticals

Indian pharmaceutical companies are still considering expansion into phytopharmaceuticals even as they are well-positioned to tap into a promising market driven by consumer demand for natural, sustainable, and health-focused products. The Union government's regulations on phytopharmaceuticals focusing on the scientific data, quality, safety, and efficacy of a herbal drug on similar lines to synthetic, chemical moieties can give the companies a head start. Further, the production linked incentive (PLI) scheme has brought phytopharmaceuticals under its ambit which companies need to maximise.

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Pharma export grows over 9% in September

Exports of pharmaceutical products from the country have reported a 9.01 per cent growth during the month of September as compared to the same period of previous year. For the first six months of the current fiscal year, the exports have posted a 5.02 per cent growth.According to data from the Central Government, the exports during the month of September, 2023 stood at $2.39 billion as compared to $2.19 billion during the same month of last year.The growth compared to the exports of $2.24 billion in the previous month of August is around 6.7 per cent.

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Venus expands global reach with launch of Elores in Ecuador

Going by its ability to formulate products with advanced technologies including modified drug Venus Remedies Limited, a leading pharmaceutical company known for its commitment to innovation and healthcare excellence, has announced the successful launch of Elores in Ecuador. This significant expansion follows the earlier launches of Elores in countries like Saudi Arabia, Myanmar, Oman, Tanzania, Ethiopia, and India, marking a momentous stride in the company's global growth. Additionally, the dossier has also been submitted in around 15 countries for getting the marketing authorisations.

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