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NEWS LETTER
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India's First Locally Developed Wet AMD Drug Awaits Final Regulatory Nod

A locally developed product for wet AMD (age-related macular degeneration) is hopeful of being commercialised in India in early 2025 through a local collaboration between Mumbai's Vav Life Sciences and Madurai's Aurolab Trust, the manufacturing division of Aravind Eye Hospital.

The product awaits a final regulatory approval from the Central Drugs Standard Control Organisation (CDSCO) and will be less expensive and "more bio-available (better absorbed into the body)", said Arun Kedia, Managing Director of Vav Life Sciences told businessline. The formulation uses VAV's synthetic phospholipid for better delivery of the drug, he explained.

The product involves an intravenous liposomal Verteporfin injection, along with photodynamic therapy (light), to treat AMD. According to industry insiders, there are no locally made products to treat wet AMD. The existing product in this therapeutic segment is imported at about ₹70,000, a company official said.

The product is a first in the country, says Kedia, adding that "all development work including cell line studies, in-vivo evaluations and long term stability trials are completed." It has been developed by the inhouse scientific team of Aurolab, with inputs from VAV's nanotechnology scientists, he added.

VAV is a nanotechnology research-based company that makes lipids used in drug delivery and during Covid-19, it was among four global companies making phospholipids for mRNA Covid-19 vaccines.

While the CDSCO's response is awaited, he said, the Aurolabs team is working on its manufacturing capacity, as the entire product would have to be produced at the site. The hospital's approach has been to produce treatment free or at subsidised rates, and that philosophy would prevail with the latest product as well, said Kedia, adding that discussions on pricing, etc., would be revealed by them after the regulatory approval is received.

AMD is a global concern, with a largely ageing population particularly vulnerable to the condition. Another company, Eyestem, is presently undertaking trials in India for its potential product for dry AMD. In April.

The CDSCO green-lighted clinical trials on the product aimed at addressing geographic atrophy arising from dry AMD, the company said. (Source: Business Line)

Akums Inks €200 Million Agreement With a Global Pharma Company For The European Market.

Akums Group has inked a long-term agreement with a global pharmaceutical company to manufacture and supply formulations in the European market.

The total value of this agreement is estimated at €200 million (₹1,760 crore), the company said, adding that Akums would receive an upfront payment of €100 million (₹880 crore) for product development and site approval from the European authorities.

Growth plans

A contract manufacturing and development organisation (CDMO), Akums, will produce and supply multiple SKUs of oral liquid formulations, which the partner company will market across various European countries. The agreement is in line with its growth plans to expand in Europe and other regulated markets, alongside local manufacturing.

This agreement helps boosting domestic manufacturing capabilities for global markets, the company said, adding that commercial supply of these products was expected to begin in 2027 and continue till 2032.

As part of this pact, Akums will initiate the European approval process for its oral liquid manufacturing facility, to produce the contracted products. The site and product dossier approvals are expected to be received by end 2026. Akums already operates two European-approved facilities for injectables and oral solids, it added.

Collaboration opportunities

Sanjeev Jain, Akums Managing Director, said, the agreement opened doors for the company to further expand its footprint in the regulated markets and "replicate the domestic CDMO success globally." "These products are currently being manufactured in Europe.

The Manufacturing these products in India opens further collaboration opportunities with other global pharma companies to optimise their manufacturing costs and make their supply chain robust. ...Akums already has European approved facility for tablets, hard gelatin capsules, sachets, ampoules, vials, eye-drops and dry powder injection," he added. (Source: Buiness Line)

Pharma Backs Move To End Plastics Pollution

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Global Self-Care Federation (GSCF), and the International Generic and Biosimilar medicines Association (IGBA) have jointly said that they support an international instrument to end plastics pollution.

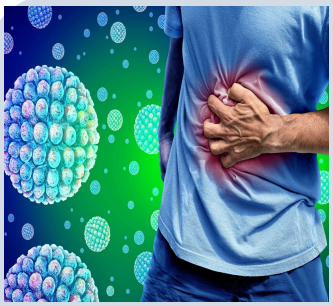
Plastics play an essential part in public health "by enabling the availability of safe, effective, and quality-assured medicines for patients around the world", they said in a joint note.

The greatest potential impact of the instrument will be on medicinal products, where plastic packaging (primary packaging) or a device made from plastic is in direct contact with a medicinal product, or on plastic products used in the manufacturing process.

There are specific considerations for the health industry, due to stringent regulatory rules, to ensure that materials meet rigorous quality, safety, and efficacy standards to protect patient health.

Changes require time and resources, from industry and from national regulatory agencies, to be implemented, they said, adding that testing and validation of innovative packaging material can take 5-10 years to complete. (Source: Business Line)

UK Health Services Under Strain After Record Fu, Norovirus Cases



Hospitals are dealing with quadruple the number of flu cases they were last year. Concerns have been raised over a rising number of flu and norovirus cases (PA) Health experts have sounded the alarm as the service is under unprecedented pressure, with hospitals struggling to cope with a record number of patients at this time of year.

New data shows an average of 96,587 hospital beds in England were occupied daily last week, the highest number recorded for this time of year. This means that nearly 95% of hospital beds are full, intensifying fears that the system will buckle under the weight of rising cases. An average of 1,099 flu patients were hospitalized each day last week, including 39 in critical care, a sharp increase from last year's figures of 243 hospitalizations with nine in critical care. Health leaders had already raised concerns over a potential "tripledemic" of flu, Covid-19, and RSV, but the recent surge in norovirus cases, which have jumped 86% compared to the same week last year, has prompted NHS officials to brace for a full-blown "quad-demic." The NHS is also grappling with delays in ambulance handovers, with more than a third of patients arriving by ambulance last week waiting over 30 minutes to be transferred to A&E.

Professor Sir Stephen Powis, NHS national medical director, warned that the situation will worsen as winter progresses, with the flu and norovirus numbers continuing to rise sharply. He urged those eligible for a free flu or Covid jab to get vaccinated as soon as possible to help reduce the pressure on the health service.

The NHS is busier than it has ever been before, and we are still only at the start of December," he said. Meanwhile, Patricia Marquis, executive director for England at the Royal College of Nursing, said there is "barely a spare bed" in the NHS, and thousands of patients are unable to be discharged due to a lack of capacity in social care. "Staff and patients are desperately worried about what the coming weeks and months may bring," she added.

The latest figures also show that 7.57 million treatments were waiting to be carried out at the end of September, with 249,343 people waiting more than a year for routine hospital treatment. This backlog, combined with surging admissions, has raised concerns about the NHS's ability to meet key waiting time targets set out in the Government's "plan for change," which aims to have 92% of patients seen within 18 weeks for pre-planned care by July 2029. While Prime Minister Sir Keir Starmer expressed optimism about the Government's long-term vision for the NHS, health commentators have called for a "healthy dose of realism," highlighting the challenges posed by increased patient demand, workforce shortages, and a decade of underinvestment in the system. (Source: Hindustan Times)

Novartis Cannot Block Generic of Best-Selling Heart Drug, US Appeals Court Says

Novartis failed to persuade a U.S. appeals court on Wednesday to halt MSN Pharmaceuticals' proposed generic of Novartis' blockbuster heart drug Entresto. The U.S. Court of Appeals for the Federal Circuit upheld a Delaware federal judge's August decision that found Novartis failed to prove it was likely to win a patent lawsuit against MSN over the drug, removing a roadblock for MSN's launch of what would be the first U.S. Entresto generic.

Novartis said in a statement that it disagrees with the ruling and is "considering all available options to vigorously defend our intellectual property rights, including further appellate options." Spokespeople and attorneys for MSN did not immediately respond to a request for comment. Entresto is Switzerland-based Novartis' best-selling drug, bringing the company more than $6 billion in revenue last year. MSN's version of Entresto was approved by the U.S. Food and Drug Administration in July.

Novartis sued MSN and others seeking to launch Entresto generics in Delaware federal court in 2022 for allegedly infringing a patent that expires in 2026. It requested a preliminary injunction after the FDA's approval that would block MSN from launching its generic during the case, which is set to go to trial on Monday.

U.S. District Judge Richard Andrews rejected Novartis' request in August, ruling that it was not sufficiently likely to win on its infringement claims to justify the injunction. The judge paused MSN's launch of its proposed generic while Novartis appealed to the Federal Circuit. (Source: Reuters)

Healthcare Stocks Fall As Lawmakers Push For Bill To Break Up Drug Middlemen

Shares of companies owning pharmacy benefit managers fell on Wednesday after the introduction of a bipartisan bill that would force health insurers or drug middlemen to divest their pharmacy businesses.

CVS Health's Caremark, Cigna's Express Scripts and UnitedHealth Group's Optum control the majority of pharmacy benefit management (PBMs) in the US, while their parent companies also operate health insurance businesses. Shares of all three companies were down between 4.8% to 5.5% after the Wall Street Journal first reported news of the bill.

The bill, sponsored by U.S. Senators Elizabeth Warren, a Democrat, and Josh Hawley, a Republican, will force companies owning health insurers or pharmacy benefit managers to divest their businesses operating pharmacies within three years. Representatives Diana Harshbarger, a Republican, and Jake Auchincloss, a Democrat, are also supporting the bill, which will be introduced in the Congress.

PBMs negotiate prescription drug prices between insurers, pharmacies and drugmakers, and directly reimburse pharmacies for prescription drugs included under their agreed terms.

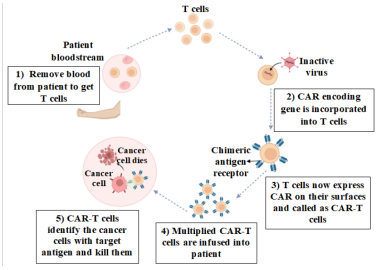
They have previously come under scrutiny for their influence over prescription drug prices.

"PBMs have manipulated the market to enrich themselves — hiking up drug costs, cheating employers, and driving small pharmacies out of business. My new bipartisan bill will untangle these conflicts of interest by reining in these middlemen," said Senator Warren.

Shares of other insurers such as Elevance , Humana and Centene fell between 1% and 3%. "The latest introduction of potential legislation to restrict PBM operations and broader healthcare vertical integration is unlikely to gain traction, although it is hard to dismiss outright," said Leerink Partners analyst Michael Cherny.

Shares of insurers have come under pressure after Brian Thompson, the CEO of UnitedHealth's health insurance unit, was fatally shot outside a Manhattan hotel last week. (Source: Reuters)

How The Pharma Industry is Bringing In Novel Antibiotics And Affordable Car-T Therapy



In this episode of the State of Economy Podcast, businessline's Jyothi Datta speaks with Sudharshan Jain, the Secretary General of the Indian Pharmaceutical Alliance (IPA), as they reflect on the achievements and challenges of India's pharmaceutical industry in 2024.

As the world's pharmacy, India continues to make a global impact, providing medicines to over 200 countries. Jain outlines key highlights of the year, including the country's progress toward self-reliance in Active Pharmaceutical Ingredients (APIs) and the success of government initiatives like the Production Linked Incentive (PLI) scheme.

Jain discusses the critical issues such as the need for enhanced quality standards and innovation in the pharmaceutical sector, the ongoing efforts to tackle counterfeit drugs, and India's role in supplying affordable medicines globally. Jain emphasises the importance of quality control, the introduction of new medical technologies, and the growing role of Indian companies in the development of biosimilars and mRNA vaccines.

Looking ahead to 2025, Jain shares his perspective on how India can strengthen its export market amidst geopolitical shifts and increasing global demand for affordable healthcare solutions. He also talks about how the pharmaceutical industry can contribute to government programs aimed at improving access to medicines, such as the Janaushadhi Scheme ad Ayushman Bharat scheme and ensuring that healthcare reaches underserved rural areas. (Source: Business Line)