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NEWS LETTER
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India Bans Another 156 Fixed Drug Combos Over Safety Concerns

India's drugs standard control organisation has banned 156 popularly used fixed drug combinations, also called cocktail drugs, citing them as "irrational combinations"; that could have adverse effect on human health.

The drug combinations are used across ailments ranging from skin care, treating allergies, fever, acne, among others. Vastly used hair growth formulations have been banned too.

Popular combinations involving cetirizine – that include cetirizine HCI, paracetamol and phenlephrine (used to treat common cold and allergies), cetirizine and phenylephrine (another anti-allergic), among others – have been banned.

Popular skin-care combos – aloe (vera) and Vitamin E combination of medicated soaps; calamines-based cocktail drugs like calamine – aloe – allantoin, calamine – diphenhyramine hydrochloride – aloe-glycerine – camphor, among others stand banned too.

A popular combination of mefenamic acid and paracetamol - used to treat inflammation, migraine, headaches, toothaches, etc – has also been banned.

Minoxidil based combos, that are used to treat hair loss or are often used to claimed as hair regeneration / growth formulations have been banned. For instance, combinations involving minoxidil - azelaic acid - saw palmetto, minoxidil – aminexil – alcohol, minoxidil – aminexil, etc are to be withdrawn with immediate effect.

The newly banned cocktail drugs include levo-cetirizine and phenylephrine hydrochloride; paracetamol and pentazocine; and paracetamol, diclofenac potassium and caffeine anhydrous

Some of the drug combinations now prohibited were also a combination of commonly used active pharmaceutical ingredients (API) with herbs such as ginkgo biloba, and a mix of vitamins and enzymes.

The list also banned multi-enzyme complexes containing as many as 12-15 enzymes and over 20 formulations containing naphazoline, a decongestant commonly used in eye drops.

"Most of these drugs are in usage for over 10-15 years. And none of the banned ones are new drugs. Our committees found that these drugs have no therapeutic value or there was any scientific justification of these combos," a Health Ministry official said adding that these drug combinations are used by a variety of pharma companies, and in some cases, used by products sold over the counter (OTC).

Some have previously been withdrawn by manufacturers already.

According to the official, State counterparts of the Central Drugs Standard Control Organisation (CDSCO) and other licensing authorities in States have been told not to grant approvals for any new drug(s) or combos. These have to be approved by the Centre.

The official added, that the current ban is a part of the larger drive that was set in motion post 2012. A report of the Parliamentary Standing suggested examination of drug combos licensed by the State Licensing Authority without prior approval of Drug Controller General of India (DCGI).The Kokate Committee subsequently set up made suggestions on prohibition of various drugs. In all, 3,450 drugs were brought under its review and around 343 combinations have been prohibited previously. (Source: Business Line

Small and medium drug makers have written to Union Health Minister JP Nadda, seeking a two-year extension to adhere to the revised Schedule M norm, that outlines Good Manufacturing Practices (GMP). Drugmakers with a turnover of ₹250 crore or less had till December 2024 to adhere to the revised Schedule M of the Drugs and Cosmetics Rules (1945), which covered multiple factors including raw materials, processes, people etc. Those over ₹250 crore had till July 2024 to come up to speed with these norms. In fact,

Indonesia Court Finds Drugmakers At Fault Over Toxic Cough Syrup, Awards Parents

An Indonesian court ordered two local companies to pay up to 60 million rupiah ($3,850) to each family whose children died of an acute kidney injury or were seriously injured after consuming toxic cough syrup.

More than 200 children in Indonesia died of the injury and about 120 more survived, some of whom lived with disabilities which led to financial hardships for their parents.

Indonesian courts have cited lax oversight by pharmaceutical companies, including local drugmakers and some suppliers, as well as the country's food and drugs agency (BPOM), in hearings into the poisonings.

In late 2022, more than 20 families launched a civil suit against the agency, the health ministry, and several companies. Judges at the Central Jakarta court found a drugmaker and a supplier, Afi Farma and CV Samudera Chemical, at fault in the poisonings, according to a ruling released late on Thursday.

The health ministry and the BPOM were cleared of wrongdoing. The court ordered the companies to pay the parents who brought the suit compensation 50 million rupiah for children who died and 60 million rupiah for children who were injured.

Parents had asked for 3.4 billion rupiah for each child that died, and 2.2 billion rupiah for survivors. Indonesia's 2023 gross domestic product per capita was nearly $5,000, data from the country's Statistics Bureau shows. Siti Habiba, the lawyer for the parents, did not immediately respond to a request for comment. The court document, posted on its website, did not include reasons for the decision. Here is Sudanese health minister Haitham Mohammed Ibrahim.

Afi Farma's lawyer Reza Wendra Prayogo told Reuters on Friday the firm was "disappointed" with the civil case ruling and the company was still considering its next legal step. Last year, a criminal court found East Java-based drugmaker Afi Farma guilty of negligence and jailed officials for not testing the ingredients sent by its supplier. The syrups contained ethylene glycol (EG), a commonly used chemical in products such as brake fluid and antifreeze. A court document from that criminal case said the EG concentration in the syrups reached as high as 99%, where international standards say only 0.1% of EG is safe for consumption. (Source: Reuters)

AstraZeneca Says Lung Cancer Drug Trial Shows No Significant Improvement in Overall Survival

Detailed results from one of AstraZeneca's key lung cancer trials released on Monday showed that its experimental precision drug did not significantly improve overall survival results for patients in the trial.

The overall survival, or OS rates, in the TROPION-Lung01 trial "did not reach statistical significance", the company said in a presentation at the World Conference on Lung Cancer in San Diego.

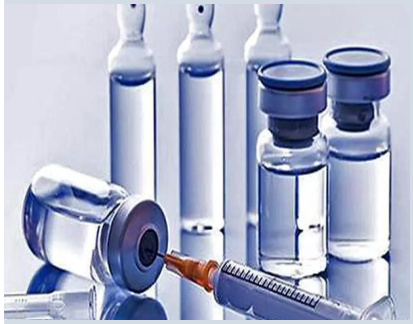
The late-stage trial has been closely watched by investors and by analysts who forecast that the drug, known as Dato-DXd, could potentially be another best-selling medicine for the company.

The trial compared the two treatments -- AstraZeneca's drug and chemotherapy -- of patients whose non-small cell lung cancer had returned after one or two prior treatment attempts.

Previous data releases related to the trial have knocked shares. In July 2023, the drugmaker's shares fell by as much as 8% after the company released interim data on progression-free survival, or PFS. And they fell again later in the year after the company released more PFS data related to the trial.

Overall survival is another important efficacy criterion for cancer drugs. The drug, known as Dato-DXd, belongs to a promising class known as antibody drug conjugates (ADC), which consist of tumour-seeking monoclonal antibodies that are combined with a cell-killing chemotherapy payload. It has been developed jointly with Japan's Daiichi Sankyo. (Source: Reuters)

Small And Medium Drug Makers Seek Two-Year Extension On Revised Schedule M Norms



The Health Ministry was also reported to be looking at aligning drug approvals with adherence to these norms. Explaining the call for extension up to December 2026, the Federation of Pharma Entrepreneurs (FOPE) President Harish K. Jain told business line, the final notification (2023) had not taken on board suggestions from pharma associations representing small and medium drug makers, and in fact, more compliance features were added.

The document had features that are rigid, in terms of process for example, rather than looking at the outcome, he explained, and there was little margin given for remediation efforts, he claimed. The industry platform representing small and large entrepreneurs asked for part of the norms to be kept voluntary – in terms of product recall, quality guidelines etc.

Countering the view that stringent norms would prevent low-quality products from being sold in the country and abroad - the Gambian cough-syrup linked tragedy being a case in point, Jain said, the company named in the international incident had GMP and WHO certifications. It all comes down to enforcement, he said, adding that closures had been ordered of several manufacturers, based on the present GMP norms.

In their letter to the Health Minister, FOPE said, “Revised Schedule M is largely based on WHO GMP. WHO GMP is a dynamic guideline .... Hence, not mandatory. In view of the same, Part I of the GSR 999 (E) notification may be made mandatory, however, other parts may be issued only as a guideline and flexibility to be given to the manufacturers to adopt various alternative technologies to achieve the final objective.” The association pointed out, “About 20 percent of the country’s total manufacturers comply with WHO GMP requirements and out of the rest, most of them will face closure if revised Schedule M is implemented without adequate time and handholding ...”

The letter called for a graded approach to non-compliance observed during inspection - in that, it be classified as critical, major and minor as is the practice globally, and the licensee be given time to perform corrective and preventive action. “Penal action should be taken only if the licensee fails to comply satisfactorily with the observations and to take CAPA,” they said. The proposed financial support outlined by the Department of Pharmaceuticals towards upgradation of facilities to meet cGMP norms, also needed to be revisited, the letter said. (Source: Business Line)

Lilly's Weight-Loss Drug Cuts Diabetes Risk in Overweight Patients

Eli Lilly's weight-loss drug, Zepbound, drastically cut the risk of developing type 2 diabetes in overweight or obese pre-diabetic adults after three years of weekly injections, the drugmaker said on Tuesday. Shares of Lilly rose 4.4% to $962.02 in early trading, adding to an over 60% rise in stock value this year.

In a trial involving 1,032 adults, patients who were on weekly injections showed a 94% reduction in the risk of progression to type 2 diabetes, compared with placebo, Lilly reported in a statement.

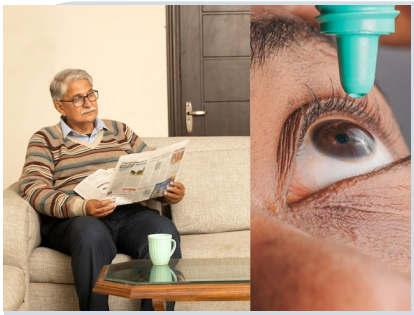
"We just don't see numbers like this in metabolic space," BMO Capital Markets analyst Evan Seigerman said. He added that Novo's drug had also showed a 73% risk reduction after three years in a separate late-stage trial. The Indianapolis, Indiana-based company said the data comes from the longest completed trial of the drug, and reinforces the long-term benefits of tirzepatide - the chemical name of its Zepbound and Mounjaro treatments.

Both Eli Lilly and rival Novo Nordisk have been pushing to extend the use of their obesity drugs to related conditions, which would help expand the patient pool and gain wider insurance coverage. Early results from its late-stage trial, "SURMOUNT-1", were initially disclosed in 2022. The data at that time showed the drug helped cut weight significantly in obese patients, helping it to secure U.S. regulatory approval.

It was unclear if the company could file for approval to prevent diabetes based on the data, Leerink analyst David Risinger said.

A pre-diabetes approval, however, could be a big upside for the stock, he added. Lilly also said patients began to regain weight and showed some increase in the progression to type 2 diabetes when they stopped treatment during the trial. Detailed data would be presented later, it said. (Source: Reuters)

Should You Go For PresVu Eye Drop Over Reading Glasses? Here's What Doctors Advise



This week, Mumbai-headquartered Entod Pharmaceuticals launched eye drops that can eliminate the need for reading glasses. India's first eye drops to remove the need for reading glasses, PresVu, have been approved by the drug regulatory agency after deliberating on it for more than two years. The medicine has received commercialisation approval from the expert committee and Central Drugs Standard Control Organisation (CDSCO) after submitting the data from a phase 3 clinical study on over 270 patients.

Nikkhil K Masurkar, chief executive officer (CEO) of Entod Pharmaceuticals, earlier told News18 in an exclusive interview that the drug will hit shelves in October and will be a prescription-based medicine.

The medicine is being pitched as a solution to remove reading glasses. However, multiple eye experts told News18 that in the real-world scenario, replacing spectacles with reusable eye drops may not be a good idea in the long run. They said that the drops can offer a stop-gap arrangement but not a lifetime solution or miracle cure.

HOW DOES THE MEDICINE WORK?

The medicine is made using 'pilocarpine' which has been used in the treatment of glaucoma for the last 75 years. The medicine treats Presbyopia by reducing the size of the pupils which helps to see objects up close. Presbyopia is the age-linked decline in the ability of the eyes to focus on nearby objects and this condition typically becomes noticeable around the mid-40s and worsens until about the late 60s.

In healthy eyes, the clear lens behind the iris adjusts its shape to focus light on the retina, creating a clear vision for near-vision tasks. This accommodation is the ability of the natural lens in the eye to change its focusing power to see clear objects. This accommodation is maximum at a young age but decreases with age, requiring near glasses with convex lenses to see fine print at 33/40cm. These eye drops improve visual clarity by modulating the pupil, creating a "pinhole effect" that increases the depth of field and improves the ability to focus on nearby objects.

In foreign countries, there are a few medicines for Presbyopia treatment, such as Orasis Pharmaceuticals' Qlosi and AbbVie's VUITY approved by the US Food and Drug Administration (US FDA). In 2021, VUITY was the first and only FDA-approved eye drop to treat presbyopia in the world.

NOT A LONG-TERM SOLUTION: EXPERTS

A single drop of the medicine starts working in just 15 minutes and its effects remain for the next six hours. If the second drop is also poured within three to six hours of the first drop, the effect will stay even longer, up to nine hours. According to Dr Rohit Saxena from Dr Rajendra Prasad Centre for Ophthalmic Sciences at All India Institute of Medical Sciences, New Delhi, the drops are good for the short-term but do not offer a long-term solution.

"It is a temporary solution for reading problems as the effect of the drug will last for 4-6 hours and the drops will be needed 1-2 times a day lifelong," he said. "I would still consider spectacles as the preferred long-term solution as some side effects are also associated with the medicine, which include blurred distance vision, headache and rarely retinal detachment."

Dr Digvijay Singh, head of the department, ophthalmology at Narayana Superspecialty Hospital, Gurugram, said the use of these drops is like flogging a tired horse. "The horse will run a little bit but eventually, it will tire off and fall." "Similarly, the drops will help for an interim period but eventually, the weakened muscles will tire out and you need to wear glasses," he said, adding that these drops can work as a "stop-gap arrangement" but not as a "miracle cure".

Dr Samir Sud, co-founder and director of Sharp Sight Eye Hospitals, believes that the usage of these drops is slightly "impractical" for the entire life and success of medicines in clinical trials is just half the battle won. Top, as he Sets Forth Upon his 45th Apostolic Journey "We need to wait and watch how the drug behaves when it is used by masses. Also, it is quite impractical that you need to keep reusing the drops for its effects as it's not a one-time solution." Sud explained that there are many other practical solutions such as multifocal lenses which give the same effect. "Only time will tell if these eye drops are useful for daily usage or not."(Source: News 18)