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NEWS LETTER
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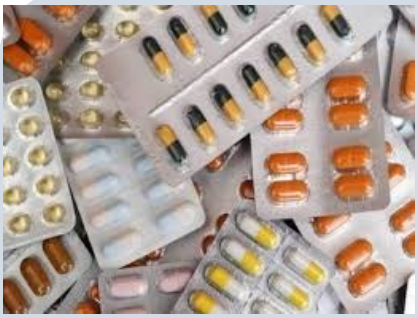
Rampant Fakes Of Lifesaving Drugs found In Delhi, Jharkhand



India's apex drug regulator has warned consumers about spurious copies of five potentially lifesaving medicines being sold in the market, as well as 50 other drugs that it said were not of standard quality.

The Central Drugs Standard Control Organization heightened inspections in the domestic pharmaceutical market after India-made cough syrups were linked to the deaths of children in Uzbekistan and Gambia.

Following recent inspections, drug authorities found 12 outlets in New Delhi involved in the distribution of spurious drugs, including one at Bhagirath Place, a wholesale market distributing medicines across India.

Increased risk of morbidity

CDSCO, in its alert for April, reported finding spurious versions of these five drugs in the market:

- Anti-HIV medication Dolutegravir tablets IP 50 mg
- Telmisartan 40mg and Amlodipine 5mg tablets IP used for the management of high blood pressure
- Domperidone and Naproxen Sodium tablets, used to manage migraines and pain
- Rifaximin tablets, used for treating diarrhoea and liver disease
- Cefixime Trihydrate with Lactic Acid Bacillus tablets LP, used to treat bacterial infections

"'Not of standard quality' and spurious drugs can cause treatment failure and adverse reactions, increase the risk of morbidity and mortality, and lead to drug resistance," said a state drug controller, requesting anonymity.

"Poor-quality medicines also increase healthcare costs to patients and the health system, wasting resources that could otherwise be used to benefit public health."

A central database

Drugs Controller General of India, Rajeev Raghuvanshi, on 9 February directed state drug licensing authorities to routinely analyse drug samples and keep a strong vigil on medicines available in the market.

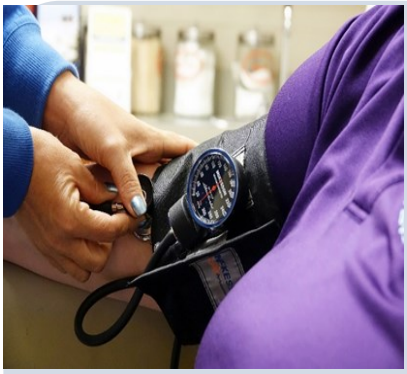
Following inspections, state drug authorities verify samples with the manufacturer to confirm the authenticity of the medicines. Information from the state authorities are logged in a centralised monthly database of spurious and medicines deemed 'not of standard quality'.

"Prior to this, there was no centralised database of sale outlets where NSQ/spurious products were reported. Such identified outlets are to be kept for regular vigilance" said the state drug controller quoted earlier.

"Whenever a drug inspector collects the samples, he checks the quality and efficacy of drugs and cosmetics available in the market with their approved specifications," the official said.

"This process involves monitoring the quality of the (active pharmaceutical ingredients), excipients, and finished products of drugs, cosmetic and medical devices in all parts of the distribution chain throughout the authorised shelf life." The CDSCO in its latest communication said the state drugs licensing authorities of Mizoram, Tripura, and Pondicherry had reported nil findings of spurious drugs in April. However, most other states, including Andhra Pradesh, Bihar, Gujarat, Maharashtra, Tamil Nadu, and West Bengal, have not submitted their findings. (Source: Mint)

U.S. healthcare spending rises to $4.8 trillion in 2023, outpacing GDP



WASHINGTON, Healthcare spending in the U.S. is projected to have risen 7.5% in 2023 to $4.8 trillion, federal data showed on Wednesday, outpacing the projected annual gross domestic product growth rate of 6.1%.

Spending on Medicaid and private health insurance drove the growth, with the insured share of the population surging to a historic high of 93%, data from the U.S. Centers for Medicare and Medicaid Services (CMS) showed.

The number of insured individuals largely grew due to record high enrollment in Medicaid, with 91.2 million people being covered under the federal and state health program for the poor in 2023. Medicare spending is projected to have grown by 8.4% to over 1 trillion and the Medicaid by 5.7% to $852 billion. Spending on private health insurance is projected to have grown by 1.1% to $1.4 trillion.

The estimated healthcare spending per person in the U.S. stood at about $14,423 in 2023 and $15,074 in 2024. National health spending is expected to grow by 5.2% in 2024, though Medicaid enrollment is set to decline by 11.2% when over 10 million people lose coverage now that pandemic response measures guaranteeing continuous enrollment have expired.

An estimated further 2 million will lose coverage in 2025. Spending is set to grow an average of 5.6% a year between 2023 and 2032, outpacing the projected annual gross domestic product growth rate of 4.3% during the same period.

The rise will lead to an increase in the health spending share of growth domestic product to 19.7% by 2032 from 17.3% in 2022, the data showed. Spending in the Medicare program for people over the age of 65 and the disabled is set to initially grow during the coming decade partially due to measures in President Joe Biden's signature Inflation Reduction Act which among other provisions introduced a $2,000 annual cap on out-of-pocket spending.

It will gradually fall over the following years when the effects of other provisions kick in, such as drug prices negotiated by Medicare with pharmaceutical companies that are set to apply starting 2026, and the tying of drug price increases to inflation which already started in 2023. (Source: Reuters)

India Panel Urges Drug Regulator To Approve Lilly's Obesity Drug Mounjaro

An Indian government-approved expert panel has advised the country's drug regulator to approve the import and sale of U.S. drugmaker Eli Lilly's Mounjaro, a blockbuster diabetes drug and a wildly popular obesity treatment, a document on a government website showed on Monday.

Lilly's Mounjaro, chemically known as tirzepatide, and Zepbound and Danish rival Novo Nordisk's Wegovy and Ozempic belong to a class of therapies known as GLP-1 receptor agonists, developed to control blood sugar in patients with type 2 diabetes.

They also slow digestion, helping patients feel full longer, making them a wildly popular choice for weight loss.

"After detailed deliberation, the committee recommended for grant of permission for import and marketing" of certain doses of tirzepatide "for chronic weight management subject to the condition that firm should conduct Phase 4 clinical trial (post-marketing surveillance)," the Subject Expert Committee said in a notification dated June 19.

The committee advises India's drug regulator on approvals of drugs and trials. "A recommendation from the subject expert committee is like the penultimate step of the approval," said Sheetal Sapale, vice president of research firm Pharmarack.

Lilly did not immediately respond to a Reuters request for comment. CEO David Ricks had told Reuters a few months back that the company expected to launch Mounjaro in India as early as next year.
India has the world's second-highest number of people with type 2 diabetes and high obesity rates. Around 11% of Indian adults will be obese by 2035, per the World Obesity Federation Atlas. The global weight-loss drugs market is estimated to reach at least $100 billion by the decade's end. Lilly should also submit the required manufacturing and controls data, the expert panel added. (Source: Reuters)

Identity Crisis. The Menace of Look-Alike, Sound-Alike Drugs

The very existence of countless misleading brand names shows that India's drug regulator, Central Drugs Standard Control Organisation (CDSCO), is not doing what it is tasked to do, a recent study in Lancet Regional Health noted.

In India, drug regulation is lax, as noted in the book The Truth Pill which deals with the 'myth of drug regulation in India'. Adding to that is the problem of doctors not writing prescriptions legibly, although they are required to do so by law. Overlaying these is yet another issue — that of 'look-alike, sound-alike', or LASA, drugs. You could, especially in situations where the pharmacist is not trained, asking for one drug and getting another.

The World Health Organisation is seized of the problem. In a technical document of October 2023, the global health watchdog notes that "Look-alike, sound-alike (LASA) medicines are a well-recognised cause of medication errors that are due to orthographic (look-alike) and phonetic (sound-alike) similarities between medicines, which can be confusing. Confusions can occur between brand-brand, brand-generic or generic-generic names."

There are a lot of LASA drugs in India. We do not know what harm they are causing because we are not even aware of them, leave alone a study. Indian drug laws require the drug regulatory body to review a trademark search to ensure that there are no misleading brand names before granting marketing authorization for a drug. However.

The very existence of countless misleading brand names shows that India's drug regulator, Central Drugs Standard Control Organisation (CDSCO), is not doing what it is tasked to do," says a recent scientific paper published in The Lancet Regional Health – Southeast Asia, authored by Murali Neelakantan, Parth Sharma and Ashish Kulkarni. LASA drugs may lead to significant medication errors and could quite conceivably result in harm to the patients, the paper notes, calling LASA "a significant public health threat". The paper gives some telling examples of drugs having same names but manufactured and marketed by different entities.

"For example, (i) brand name 'Medzol' is used for both Midazolam and Pantoprazole; (ii) 'Medzole' is used for Metronidazole oral suspension, Itraconazole capsules and Albendazole tablets; (iii) 'Flucor' is used for both Fluconazole and a combination of Flupentixol and Melitracen; and (iv) 'Linamac' is used for both Lenalidomide and Linagliptin." In such cases, there is no way a pharmacist could tell which drug the doctor had prescribed (in general, prescriptions in major parts of India only mention brand names with no mention of diagnosis or treatment protocol, Neelakantan et al, say.

If you check out the medindia website, you will find an astounding number of LASA drugs. Here are some examples: These are just some examples, but the list is big. Worse, there are LASAs produced by the same manufacturer. Examples: "Confusions can occur between brand-brand, brand-generic or generic-generic names. Organizations need to prospectively design and implement strategies to identify LASA medication errors and build a robust system that intercepts them before they result in patient harm," says WHO.

"The regulator seems to have left it to pharma companies to fight each other in trademark battles to resolve the issue of misleading brand names," the paper says.

Speaking to Quantum, Neelakantan observed that there were LASA drugs — Olvance and Oleanz for hypertension and schizophrenia respectively. Even worse is the brand name 'Linamac' which is used for both Lenalidomide (treating cancer) and Linagliptin (for diabetes). "Imagine what would happen if you took one for the other," he said. Noting that the situation could be easily remedied, Neelakantan said that for starters doctors should be mandated to also write the generic names of the drugs (like paracetamol or amoxicillin) as well as the diagnosis.

The purpose for which the drug was being prescribed (like cancer or diabetes). From the regulator's side, authorization should be given only for unique brand names after checking that they do not sound similar or look alike another drug. He also called for 'tall man lettering', where the possible misleading letters are highlighted to avoid confusion (such as HydrOXYzine, an antihistamine, to distinguish it from HydALAzine, an antihypertensive). (Source: Mint)

One Doctor For Every 2,000 Patients: India's Cancer Care Needs A Fix

India's cancer burden is rising rapidly, but for a majority of Indians, cancer care is inaccessible and expensive, and disease detection late. In 2022, India had more than 14.1 lakh new cancer cases and over 9.1 lakh deaths due to it, according to the World Health Organization (WHO). As per reports published in February 2024, the risk of developing cancer before turning 75 in India was 10.6%. Also, seven out of 10 cancer patients in India die due to the disease. In developed nations, only three to four patients succumb to it. The reason for such high death rates is inadequate treatment infrastructure. In India, the infrastructure for cancer treatment is limited to just about 100 towns and cities. A major issue is that most of India's cancer patients stay in towns and rural areas, while the bulk of healthcare resources are in larger cities. In fact, 40% of the infrastructure for cancer care is concentrated in the top 10 metros. Naturally, on average, a cancer patient has to travel for six to seven hours to reach the nearest treatment facility. Healthcare experts also point out that making cancer drugs available in interior parts of the country is one of the biggest tasks for the healthcare system.

Ruby Ahluwalia, founder of Sanjeevani: Life Beyond Cancer, an organisation that provides care, counselling and rehabilitation to cancer patients, says that there is a need for a holistic support system for cancer patients. "The doctor-patient ratio is approximately 1:2,000. Primary healthcare staff at government hospitals usually have little knowledge about cancer diagnosis. There is a lack of focus on spreading awareness about prevention and early detection."

Government Hospitals Need A Boost

Government or public hospitals lack the infrastructure for cancer treatment. There are only around 5,000 beds in government hospitals for lakhs of cancer patients. It's not uncommon to see long queues at hospitals like AIIMS. As per one report, at AIIMS Delhi, of the 70,000 cancer patients who register for treatment, only 37,000 are able to avail of it. Currently, there are 25 AIIMS hospitals in the country, of which only 12 are functional. In private hospitals, there are around 2,500 beds assigned for cancer patients. At charitable institutes like Tata Memorial, Mumbai, 70% of patients are treated free of cost or at a nominal cost. Around 65,000 patients are treated on a yearly basis here. The Centre's initiative of pooled procurement of essential cancer medicines has led to around 82% cost savings.

In all, roughly only around 30% of cancer patients are able to avail of treatment in government hospitals. The rest are left at the mercy of private hospitals, or worse, nothing. "Sadly, we still do not have sufficient hospitals in both government and private sectors to treat the burgeoning numbers of cancer patients. Many patients still have to travel to Tier-1 cities for advanced treatment. We need comprehensive cancer care centres in districts to serve the population," says Dr Aditya Kulkarni, senior consultant, GI- Hepatobiliary Cancer Surgery and Robotic surgery, Ruby Hall Clinic, Pune.

The National Cancer Grid

The National Cancer Grid (NCG) was set up in August 2012 to link cancer care centres across India. The Central government-funded NCG had the primary mandate of working towards establishing uniform standards of care across the country by adopting evidence-based management guidelines, exchange of expertise, and collaborative research cross centres. As part of NCG, modern technology-based cancer treatment is available at 298 hospitals in the country, of which only 50 are government hospitals. The rest are run by private hospitals and trusts. This network treats over two-thirds of India's cancer patients.

The Debilitating Costs Of Cancer Care

Given that a large number of patients come from economically distressed backgrounds, the cost of cancer drugs is a big deterrent to their access to high-quality treatment. As per a study, the cost of cancer treatment on average is around ₹ 61,216 per hospitalisation session. High out-of-pocket expenditure can result in calamitous spending for households and can potentially push families into poverty. This is especially true in a country where a large segment of the population relies on daily wages or is part of the informal sector. According to the American Society of Clinical Oncology Publications, approximately 40% of cancer costs are met through borrowing, sales of assets, and contributions from friends and relatives; these costs exceed 20% of the annual per capita household expenditure in 60% of Indian households that have a cancer patient.

Radiotherapy works well but is expensive. As per WHO, one tele-radiotherapy machine is required for 10 lakh population on average. As per that estimate, India should have 1,300 machines, but it has only 700. As many as 70% of cancer patients can be treated by radiotherapy. But since radiotherapy is expensive, only 20% of cancer patients are able to access it. "The cost of cancer treatment depends on many factors, including the type of cancer, the stage of disease and the treatments needed. Advanced treatments like cyber knife radiosurgery or robotic surgery are costly, as are newer chemotherapy agents," says Dr Kulkarni. As Ms. Ahluwalia rightly points out, "Cancer is a diagnosis that opens up multiple fronts for a patient. All of them need to be addressed for the cancer experience to become easier. Medical treatment is just one of the tools required by a patient to get cured of cancer."

In AIIMS and other government hospitals, the waiting period for patients has to be reduced. Treatment of patients needs to be prioritised based on the seriousness of their condition. Experts recommend establishing cancer care centres instead of cancer hospitals as they have specialists to address all fronts a cancer patient faces. Controlling the cost of cancer drugs and equipment, public-private partnerships in treatment and research, and addressing manpower shortages at primary health centres in villages and district headquarters, are some immediate steps that the Central and state governments have to take to arrest the tide. (Source: NDTV)