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The sweet poison:

Cough syrups manufactured in India

"Yes, and how many deaths will it take till he knows that too many people have died?"

~Bob Dylan

India witnessed yet again the greed of manufacturers and the lackadaisical approach of the government agencies towards quality control in medicines of the governmental agencies. Young children admitted with respiratory infections to hospitals in Chhindwara, Madhya Pradesh, were served poison masqueraded as cough syrups, resulting in the death of 11 children. Following the incident the government has sprung into action with suspension of the drug licenses of the companies supplying the syrups, legal action against the prescribing doctor and recalling of all offending cough syrups from the market. But will it be too little too late.

Cough syrups contain active pharmaceutical ingredients (APIs), vehicles (solvents like water, glycerine, or propylene glycol), preservatives, stabilizers, sweeteners, and other additives. The recommended solvents, glycerine and propylene glycol are expensive. Their use increases the production cost of these syrups leaving little margin for profit. Unscrupulous manufacturers substitute these with Diethylene Glycol (DEG), an industrial chemical, used as an antifreeze, in brake fluids, and certain plastics. They are sweet to taste, odourless, colourless in nature much like glycerol/ propylene glycol but far less expensive, and not intended for medicinal purpose. They are harmful, and even in small amounts, can lead to severe side effects. DEG is broken down to its active metabolites, 2-Hydroxyethoxyacetaldehyde, 2-Hydroxyethoxyacetic Acid (2-HEAA) and Diglycolic Acid (DGA), organic acids that dissociate to release H+ ions. DGA acts as a direct nephrotoxin causing mitochondrial dysfunction & ATP depletion, oxidative stress and acute tubular necrosis. Patients often develop delayed onset of encephalopathy, cranial nerve palsies (e.g., facial paralysis) and ascending paralysis. Hepatotoxicity is also frequently noted. The effects are more severe in children because of their smaller body weight and small doses may sometimes turn fatal.

In 2022, Gambia, a West African nation, reported the deaths of 70 children, less than 5 years of age, from acute kidney injury following treatment for acute respiratory infections. On investigation, four cough and cold syrups (Promethazine Oral Solution, Kofexmalin Baby Cough Syrup Makoff Baby Cough Syrup and Magrip N Cold Syrup) manufactured by a company based in Haryana, India, were found to be the common link. All these syrups were found to be contaminated with Diethylene Glycol (DEG) and Ethylene Glycol (EG). The World Health Organization (WHO) issued a global medical alert in October 2022, linking the deaths to the contaminated products. Although, the Indian authorities denied the charges initially citing no contamination in their own probe, subsequent investigations by a parliamentary committee found severe lapses by the Central Drugs Standard Control Organization (CDSCO) and the Indian manufacturer of the drugs. The manufacturing license of the company was withdrawn and the company is now facing criminal charges.

Just a few months after the Gambia incident, at least 86 children (reported by the Uzbek Ministry of Health) died after ingestion of the cough syrup "Doc-1 Max," prescribed for acute respiratory illness, these too were found to be contaminated with DEG. The manufacturer of the company was also based in Haryana, India. Following the incident, the WHO issued a medical product alert for Doc-1 Max in January 2023. Indian authorities cancelled the manufacturing license of the company and halted all production. Several officials from the Uzbek health ministry were arrested for negligence in allowing the import of the unregistered product and sentenced.

In August 2023, at least 6, with some reports claiming 12, children in Camerron died with similar complications. This time the offending cough syrup was Naturcold, manufactured by yet another Indian company. Indian drug regulator found violations in GMP (Good Manufacturing Practices)

at the drugmakers sites. The license of the manufacturer was cancelled. The probe is ongoing. Although the laws against adulteration of drugs causing deaths are strict in principal, in reality, conviction in most cases is challenging.

Despite a spate of mishaps from around the world, no lessons were learnt. Only a few days back at least 15 children were reported dead from renal failure following the treatment of seasonal cough and cold with cough syrup Coldrif. Investigations found the presence of the diethylene glycol in the samples. This time too, the Drug Control Department reported serious violations in the manufacturing practices in the factories that produced Coldrif.

What remains common to all incidents is the fact that all these syrups were manufactured in India. Who then is to be blamed? The most obvious responsibility lies with the pharmaceutical companies that substitute acceptable substances with harmful alternatives for cutting production costs. These are not cases of minor slips but cases of criminal negligence putting human life at danger. India has an elaborate system for quality control of drugs, regulated by the Central Drugs Standard Control Organisation (CDSCO). The Drug Controller General of India (DCGI) leads the CDSCO and is responsible for drug approval, setting standards, inspections to verify GMP (Good Manufacturing Practices), and coordination with state authorities. Central and Regional Drug Testing Laboratories (CDTLs and RDTLs) are responsible for checking on random samples for quality control. Although, it looks impressive on paper, lack of drug inspectors, infrastructural inadequacies and inefficient enforcement of laws leave room for errors and in such cases, unscrupulous and dangerous practices. The final important question is the responsibility of the treating physician. Many of the available combinations of cough syrups are irrational and do not provide any actual benefit to the patient. Numerous guidelines have been issued regarding their use and it is the duty of the physician to use their rationality while prescribing these drugs.

These deaths are a grim testament to the failure of the system, from the pharmaceutical industry, to the government system of quality assurance of drugs to the prescription of drugs of no real benefit. The system will need a massive overhaul, strict industry regulations, enforcement of recommendations, employment of drug control officers, pharmacovigilance, strictures laws for adulteration of medicines, and regular Continuing Medical Educations (CMEs), and guidelines from the physicians' associations regarding treatment. Given the fact that India is considered the "pharmacy of the world", such incidents not only tarnish the name of the manufacturer but diminishes the credibility of India as a reliable supplier of quality drugs. People come to the physicians to heal, we must be careful that this trust is not lost. Too many lives have been lost, there should be no more.

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