



WHO Issues Alert for Substandard Cough Syrups Produced in India

Why in News?

[World Health Organisation \(WHO\)](#) has raised concerns over substandard cough syrups made in India, **linked to 300 child deaths, containing high levels of diethylene glycol and ethylene glycol, posing health risks.**

- The organization has issued an alert for seven syrups produced in India, while the country's **Drugs Controller General** has mandated testing of cough syrups by specified labs before export.

What are Ethylene Glycol and Diethylene Glycol?

- Ethylene glycol and diethylene glycol are **toxic alcohols with a slightly sweet taste.**
- Contamination of cough syrups with these glycols can occur, especially in products containing **paracetamol.**
 - Paracetamol in cough syrups is good and safe for children with infections. It is a **pain killer which is good at reducing fever.**
- **Diethylene glycol and ethylene glycol are adulterants** that are sometimes illegally used as solvents in liquid drugs as an alternative to non-toxic solvents such as glycerine or propylene glycol to cut costs.
 - A fatal oral dose is around 1,000-1,500 milligrams per kilogram of body weight.
 - Toxicity can also occur with lower doses consumed over several days or weeks.
 - Symptoms of contamination **may not appear until large amounts have been consumed.**
- In addition to its use in **antifreeze, ethylene glycol is used as an ingredient in hydraulic fluids, printing inks, and paint solvents** and diethylene glycol is used in the commercial preparation of **antifreeze, brake fluid, cigarettes, and some dyes.**

What are the Risks Associated with Substandard Cough Syrups?

- **Presence of Harmful Substances:**
 - Substandard cough syrups may contain high levels of diethylene glycol and ethylene glycol, which can damage the kidneys and pose a serious health risk.
- **Unscientific Combinations:**
 - Some cough syrups may have unscientific combinations of chemical components that can interact with each other and potentially cause harm.
- **Lack of Therapeutic Relevance:**
 - Substandard cough syrups may lack therapeutic relevance, meaning they may not effectively treat the underlying condition causing the cough.
- **Adverse Effects on Children:**
 - Certain cough syrups containing codeine can be addictive and even lethal if given to children. Drowsiness, dizziness, blurred vision, nausea, and difficulty in verbalizing can also be experienced, indicating potential harm.

What are the Related Regulations in India?

▪ **The Drugs and Cosmetics Act, 1940 :**

- **The Drugs and Cosmetics Act, 1940** and Rules 1945 have entrusted various responsibilities to central and state regulators for regulation of drugs and cosmetics.
- It provides the regulatory **guidelines for issuing licenses to manufacture Ayurvedic, Siddha, Unani medicines.**
- It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the **Good Manufacturing Practices (GMP).**

• **Central Drugs Standard Control Organisation(CDSCO):**

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under **the Drugs and Cosmetics Act.**
- **Major Functions:**
 - Regulatory control over the import of drugs, approval of new drugs and clinical trials.
 - Approval of certain licences as Central Licence Approving Authority.

Major Bodies Regulating Drugs and Pharmaceutical in India				
Ministry of Health and Family Welfare	Ministry of Chemicals and Fertilizers	Ministry of Commerce	Ministry of Science and Technology	Ministry of Environment
Directorate General of Health Services (DGHS) <u>Indian Council of Medical Research (ICMR)</u>	Department of Pharmaceuticals	Patent Office	Department of Biotechnology (DBT)	Environmental clearance for manufacturing
<u>Central Drugs Standard Control Organization (CDSCO)</u> headed by Drug Controller General of India, DCGI (I) + Statutory Committees + Advisory Committees	National Pharmaceutical Pricing Authority (NPPA); Drugs (Prices Control) Order (DPCO) 2013	Controller General of Patent	<u>Council of Scientific and Industrial Research (CSIR)</u> Laboratories	

Source: TH