

Chlorpheniramine Maleate and Phenylephrine Hydrochloride

Prelims: Current events of national and international importance | Health

Why in News?

The Union Health Ministry has tightened restrictions on FDCs containing chlorpheniramine maleate and phenylephrine hydrochloride.

- Manufacturers must carry a clear warning – “FDC shall not be used in children below four years of age.”
- The restriction covers their manufacture, sale and distribution.

Fixed-Dose Combinations (FDCs) is a medicine containing two or more active pharmaceutical ingredients in a fixed proportion

- In 2023, CDSCO directed manufacturers of a particular chlorpheniramine + phenylephrine formulation to carry a warning.
- In April 2025, Restrictions were imposed on certain FDCs.
- August 2026, Warning requirement extended to all FDCs containing the two ingredients.
- **Chlorpheniramine** is an antihistamine. It can reduce allergy symptoms such as a runny nose and sneezing.
- **Phenylephrine** is a decongestant, intended to relieve a blocked nose.
- The present action specifically concerns the combination of these two drugs, not every medicine containing either ingredient individually.
- **Children vulnerability** –
 - Young children are more vulnerable to adverse drug reactions.
 - Their bodies process medicines differently from adults.
 - Incorrect dosing can have proportionately greater consequences.
- The Expert Committee and Drugs Technical Advisory Board (DTAB) found potential risks associated with these combinations.
- Safer alternatives are available for managing common cold symptoms.
- **Rules significance** - Highlights concerns over irrational or unnecessary use of multi-ingredient cold medicines in children.
- It reduces the risk of accidental overdose and reinforces the importance of age- and weight-appropriate dosing.

Central Drugs Standard Control Organisation (CDSCO)

- It is the national regulatory authority of India for pharmaceuticals, medical devices, and cosmetics.
- **Operating under** - Directorate General of Health Services
- **Nodal ministry** - Ministry of Health & Family Welfare.
- **Headquarters** - New Delhi.
- The agency is headed *by the Drugs Controller General of India (DCGI).*



Reference

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