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Government Tightens Restriction on Chlorpheniramine-Phenylephrine Cold Combinations for Children Below Four

22 August 2026 ·

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Government Tightens Restriction on Chlorpheniramine-Phenylephrine Cold Combinations for Children Below Four

22 August 2026 · 1 min read ·

✓ Every fact web-verified against primary sources

The **Ministry of Health and Family Welfare**, via gazette notification **S.O. 4595(E)**, made it mandatory for all manufacturers of Fixed Dose Combinations (FDCs) containing **Chlorpheniramine Maleate + Phenylephrine Hydrochloride** to carry a warning that the combination “shall not be used in children below four years of age,” background: notification issued August 18, 2026, widely reported August 22, 2026.

What Changed

As background, this extends a narrower restriction on the same combination first imposed on **April 15, 2025**, now applying the age-restriction warning to **all formulations** of the combination, commonly used in cough and cold remedies.

Why This Matters

The move follows the government’s continuing tightening of paediatric drug-safety regulation, a policy area under scrutiny since earlier controversies over cough-syrup-linked child deaths. For background, the restriction was examined by the **Drugs Technical Advisory Board (DTAB)** at its February 16, 2026 meeting before being formalised as a notification roughly six months later.

UPSC Relevance

This connects GS2 health governance and **statutory** bodies (DTAB) with GS3 pharmacovigilance and paediatric drug safety. A useful Mains angle examines the gap between DTAB technical recommendations and eventual gazette notification, and whether labelling mandates alone are sufficient without pharmacy-level point-of-sale enforcement.

 FACTS CORNER, KNOWLEDGE PEDIA**PAEDIATRIC COLD-DRUG RESTRICTION:**

Notification: S.O. 4595(E), dated August 18, 2026

Legal basis: Section 26A, Drugs and Cosmetics Act, 1940

Background, earlier narrower restriction: April 15, 2025

Reviewing body: Drugs Technical Advisory Board (DTAB), constituted under Section 5 of the Act

OTHER RELEVANT FACTS:

DTAB is the highest statutory technical body advising the Centre and states on drug-related matters

Sources: PIB, Ministry of Health and Family Welfare

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