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Daily PIB summary**Section 26A Restrictions on Pediatric FDC Drugs**

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WHY IN NEWS

- Government prohibited the manufacture, sale, and distribution of all Fixed Dose Combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride for children below four years of age.

WHAT IS SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940?

- Empowers the Central Government to regulate, restrict, or prohibit the manufacture, sale, or distribution of drugs and cosmetics in the public interest.
- Action is taken when a drug is found to involve risk to human beings or animals without therapeutic justification.

KEY DETAILS OF THE RESTRICTION

- Applies to all Fixed Dose Combinations (FDCs) combining Chlorpheniramine Maleate (antihistamine) and Phenylephrine Hydrochloride (decongestant).
- Follows recommendations from an **Expert Committee** and the Drugs Technical Advisory Board (DTAB).
- Mandates a statutory warning on packaging, inserts, and promotional literature explicitly stating the drug is not for children under four.

WHY IT MATTERS

- Prevents severe adverse pediatric drug reactions linked to unproven combination cold medications.
- Enforces strict statutory labeling compliance under Indian pharmaceutical regulatory law.

KEY TERMS

- **Fixed Dose Combination (FDC):** A medicine containing two or more active pharmacological ingredients combined in a fixed ratio of doses.
- **Drugs Technical Advisory Board (DTAB):** The statutory apex technical body advising Central and State governments on technical matters arising out of the **Drugs and Cosmetics Act, 1940**.

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PRELIMS FACTS

- **Section 26A** of **Drugs and Cosmetics Act, 1940** grants power to prohibit or restrict drugs in public interest.
- DTAB is a statutory body constituted under the **Drugs and Cosmetics Act, 1940**.

MAINS DISCUSSION

- Regulatory challenges in monitoring pediatric fixed-dose combinations and enforcing drug safety standards in India.

KEY DATA

- **Parent Act:** **Drugs and Cosmetics Act, 1940** - Governs the regulation of import, manufacture, distribution, and sale of drugs in India.
- **Prohibition Provision:** **Section 26A** - Specific statutory clause empowering the Union government to ban or restrict hazardous drugs.
- **Statutory Advisory Body:** Drugs Technical Advisory Board (DTAB) - Highest statutory technical body under the **Drugs and Cosmetics Act**.

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