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Fixed-Dose Combinations: How India Regulates Medicines

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Fixed-Dose Combinations: How India Regulates Medicines

A small child has a runny nose and a blocked nose. A parent picks up a cold syrup from the shop. It looks harmless. But some of these syrups mix two drugs that can harm very young children. In August 2026, the Centre made a warning compulsory on all of them. This lesson explains the order and how India controls its medicines.

The cold-medicine order, at a glance

Four facts that clear up most exam questions

01
Below 4 years

The age limit printed on the warning.

02
Two drugs

Chlorpheniramine and phenylephrine, taken together.

03
DTAB

The expert board that advised the move.

04
Section 26A

The power the Centre uses to ban medicines.



A bottle of cough syrup and a spoon. Many cold medicines mix two or more drugs in one bottle. Photo: Warp3, Wikimedia Commons, CC BY-SA 3.0.

FDCShort for fixed-dose combination. It puts two or more drugs into one medicine.
AntihistamineA drug that eases allergy signs like a runny nose and sneezing.
DecongestantA drug that opens a blocked nose.
CDSCOIndia’s national drug regulator. It checks that medicines are safe.

What did CDSCO warn about painkillers and antibiotics?

Current Affairs

On **21 September 2026**, CDSCO issued a circular on two common medicine groups. They are painkillers called **NSAIDs** and **antibiotics**. It links careless use to kidney damage and to drug-resistant germs. It is a reminder of existing rules. It is **not a new ban**.

- **Policy:** The circular warns against **indiscriminate, repeated or prolonged use** of NSAIDs and antibiotics without medical advice. *So what:* the regulator now ties everyday self-medication to avoidable kidney disease. (The Hindu)
- **Data:** NSAIDs can cut blood flow to the kidneys. They are linked to acute kidney injury, mostly in people with kidney disease, diabetes or high blood pressure. Long use is linked to chronic kidney disease (CKD). *So what:* the risk is about wrong use, not about the drugs themselves. (ThePrint)
- **Data:** In one Indian pharmacovigilance analysis of NSAID-linked CKD reports, **82%** of cases were aged 40 to 80. Diclofenac was named in **43%**. *So what:* this shows who is most at risk, though it counts reports, not all patients. (The Hindu)
- **Rule reminder:** Most NSAIDs are in **Schedule H** and most antibiotics in **Schedule H1** of the Drugs Rules, 1945. Retail sale needs a prescription from a registered doctor. *So what:* no new law was needed, because the rules already exist. (TeamLease RegTech)
- **Policy:** Doctors must prescribe only when clinically needed, in the right dose and for the right time. They must follow **antimicrobial stewardship**. Pharmacies and hospitals were also put on notice. *So what:* the duty falls on prescribers and sellers, not only on patients. (All India Radio)
- **Mains fodder:** Wrong antibiotic use lets resistant bacteria survive and spread. This is **antimicrobial resistance (AMR)**. WHO says bacterial AMR was linked to over **4.7 million** deaths worldwide in 2021. *So what:* one patient's misuse becomes a public-health risk. (The Hindu)

- **Data:** A review of 66 Indian studies put self-medication at **64.4%**. A South-East Delhi study found **35%** of 200 people self-medicated with antibiotics. *So what:* the gap is in enforcement at the pharmacy counter, not in the rulebook. (The Hindu)
- **Policy:** India launched **NAP-AMR 2.0 (2025 to 2029)** in November 2025, with a One Health approach. In August 2026, CDSCO also proposed adding four more drugs to Schedule H1 in a draft notification. *So what:* tighter control on sale records is already underway. (The Hindu)

What did the Centre order?

Current Affairs

The Union Health Ministry tightened the rules on one kind of cold medicine. It mixes two drugs: **chlorpheniramine** and **phenylephrine**.

- Every such medicine must now carry a warning. It says the medicine is **not for children below four years**.
- The warning must be on the **label**, the **leaflet inside** and all **adverts**.
- The rule covers making, selling and supplying these medicines.
- Medicines with **only one** of the two drugs are not covered.

Step by step, not overnight

- In **2023**, CDSCO asked makers of one such product to add this warning.
- In **April 2025**, limits came on some of these medicines.
- The **August 2026** order extends the warning to all of them.
- (The Hindu)

Quick check 1. Q1. True or False: The 2026 order bans every medicine that contains phenylephrine. *(True or False?)* See answer ↓

What is a fixed-dose combination?

Must Know

Think of an FDC as a two-in-one pill or syrup. Instead of two separate medicines, you get both drugs in one dose.

Two drugs, one medicine



New warning from August 2026

"Not to be used in children below four years"

Medicines with only one of the two drugs are not covered by the order.

What each drug does

- **Chlorpheniramine** is an **antihistamine**. It eases a runny nose and sneezing.
- **Phenylephrine** is a **decongestant**. It opens a blocked nose.
- Such mixes are common in cold and allergy medicines.

Why mixes can be a problem

- Many cold medicines hold several drugs. A child may get the same drug twice from two products.
- So experts say: check the **drug names** on the pack, not just the brand.

> **Quick check 2.** Q2. True or False: Chlorpheniramine is an antihistamine, while phenylephrine is a decongestant. *(True or False?)* See answer ↓

Why are toddlers at risk?

Good to Know

A toddler is not a small adult. Their body handles medicine in a different way.

- Young children are **more likely to get side effects** from medicines.
- A small mistake in the dose matters much more for a tiny body.
- India's Expert Committee and **DTAB** found these mixes could harm children below four.
- They also found that **safer options** exist.
- The US drug regulator, the FDA, gives a similar warning for very young children.

What helps a child's cold instead

- Colds are caused by viruses. Most childhood colds **clear up on their own**.
- These drugs only ease the signs. They do not cure the cold.
- Saline nose drops and plenty of fluids can ease a blocked nose.

> **Quick check 3.** Q3. True or False: Cold medicines like these cure the virus that causes a cold. *(True or False?)* See answer ↓

Think it through, before reading on. If a cold syrup only eases the signs, why might a parent still give too much?

Show the explanation

Parents want a sick child to feel better fast. So they may give another dose, or a second cold medicine. But the second product may hold the same drug. Then the child gets a double dose without anyone noticing. That is why the warning and reading the drug names both matter.

Who regulates medicines in India?

Must Know

India has a clear chain of bodies that decide which medicines are safe. Exams often ask who does what.

Body or law	What it is	Key fact
Drugs and Cosmetics Act, 1940	The main law on medicines	Controls import, making and supply of drugs
CDSCO	National drug regulator	Works under the Health Ministry
DCGI	Drugs Controller General of India	Heads CDSCO
DTAB	Drugs Technical Advisory Board	Set up under Section 5; chaired by the DGHS
DCC	Drugs Consultative Committee	Also advises the DCGI

A little history

- The 1940 Act followed the advice of the **Chopra Committee** of 1930.
- The **Drugs Rules** came in 1945.
- A **1964** change brought Ayurveda and Unani medicines under the Act.

Who heads DTAB?

- DTAB advises both the Centre and the States on technical matters.
- Its chairman is the **Director General of Health Services (DGHS)**, by virtue of the post.
- It is not headed by the DCGI. The DCGI is a member.

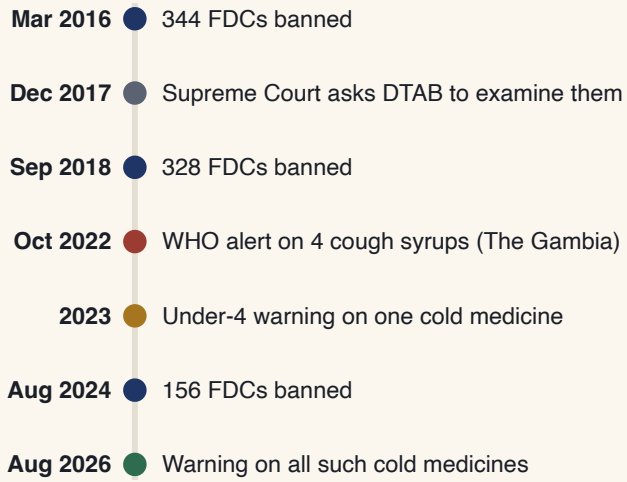
> **Quick check 4.** Q4. True or False: The Drugs Controller General of India is the chairman of DTAB. *(True or False?)* See answer ↓

How has India banned FDCs?

Must Know

India has banned hundreds of FDCs in the last ten years. The power comes from **Section 26A** of the 1940 Act. It lets the Centre ban a drug that may be risky or has no sound medical reason to exist.

A decade of action on risky medicines



Bans use Section 26A of the Drugs and Cosmetics Act, 1940.

The big bans

- **10 March 2016:** the Centre banned **344** FDCs.
- The case reached the Supreme Court. On **15 December 2017**, it asked DTAB to examine them.
- **September 2018:** on DTAB's advice, **328** FDCs were banned (Medical Dialogues).
- DTAB said their drug mixes had **no medical justification** and might harm people.
- **August 2024: 156** more FDCs were banned (The Tribune).
- One example was a tablet mixing aceclofenac and paracetamol, used for pain.

A warning from abroad

- In **October 2022**, the WHO warned about four cough and cold syrups made in India (WHO).

- They were made by a Haryana firm and found in **The Gambia**.
- They had **diethylene glycol** and ethylene glycol, which are toxic.

> **Quick check 5.** Q5. True or False: The Centre bans unsafe FDCs using Section 26A of the Drugs and Cosmetics Act, 1940. *(True or False?)* See answer ↓

Remember this: August 2026 order = warning on all chlorpheniramine + phenylephrine FDCs: not for children below four. Chlorpheniramine = antihistamine; phenylephrine = decongestant. Single-drug medicines not covered. Law = Drugs and Cosmetics Act, 1940. CDSCO is headed by the DCGI. DTAB is set up under Section 5 and chaired by the DGHS. Bans use Section 26A: 344 (2016), 328 (2018), 156 (2024).

Exam Angle

How have exams tested this?

Asked before

PYQ 1 · UPSC CDS (II) 2020, Q56

Which one of the following Indian institutes was approved by the Drugs Controller General of India for conducting human trials of the Oxford-AstraZeneca Covid-19 vaccine candidate?

(a) Bharat Biotech
(b) AIIMS
(c) Serum Institute of India
(d) National Institute of Epidemiology

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Quick Q&A

What does FDC stand for?

Fixed-dose combination.

Below what age is the cold-medicine mix not to be used?

Four years.

Which Act governs medicines in India?

The Drugs and Cosmetics Act, 1940.

Who chairs DTAB?

The Director General of Health Services.

How many FDCs were banned in August 2024?

156.

Related Topics

Indian Pharmacopoeia Commission

Healthcare Affordability and Accessibility in India

Jan Aushadhi Scheme: Affordable Generic Medicines in India

Why Multi-Drug Resistance Occurs in India

India’s First Dengue Vaccine

All General Science Articles

MCQ on Fixed-Dose Combinations and Drug Regulation

5 verified questions from this lesson.

More questions on medicines and their regulators:

- More General Science Practice

Practice MCQs

1. Consider the following statements about the August 2026 order on chlorpheniramine and phenylephrine medicines:

1. All fixed-dose combinations of the two drugs must carry a warning against use in children below four years.

2. Medicines containing only phenylephrine are also covered by the order.

3. The warning must appear on the label, package insert and promotional material.

Which of the statements given above is/are correct?

A. 1 only

B. 1 and 3 only

C. 2 and 3 only

D. 1, 2 and 3

See answer ↓

2. In a cold medicine, chlorpheniramine and phenylephrine respectively act as:

A. An antihistamine and a decongestant

B. An antibiotic and an antihistamine

C. A decongestant and an antihistamine

D. An analgesic and a decongestant

See answer ↓

3. Who is the ex officio Chairman of the Drugs Technical Advisory Board (DTAB)?

A. Drugs Controller General of India

B. Union Health Secretary

C. Director General of Health Services

D. Director General of ICMR

See answer ↓

4. Assertion (A): The Central Government can prohibit the manufacture and sale of a fixed-dose combination medicine. Reason (R): Section 26A of the Drugs and Cosmetics Act, 1940 empowers the Centre to prohibit drugs that may involve risk or lack therapeutic justification.

A. Both A and R are true and R is the correct explanation of A

B. Both A and R are true but R is not the correct explanation of A

C. A is true but R is false

D. A is false but R is true

See answer ↓

5. Arrange the following actions on fixed-dose combination (FDC) medicines in chronological order:1. Ban of 328 FDCs on DTAB's advice2. Ban of 156 FDCs used for fever, pain, cold and allergies3. Ban of 344 FDCs by gazette notification4. Under-four warning extended to all chlorpheniramine + phenylephrine FDCs

A. 3-1-2-4

B. 1-3-2-4

C. 3-2-1-4

D. 3-1-4-2

See answer ↓

6. In August 2026, the Centre required all fixed-dose combinations of chlorpheniramine and phenylephrine to carry a warning against use in children below what age?

A. Twelve years

B. Four years

C. Two years

D. Six years

See answer ↓

7. Which one of the following Indian institutes was approved by the Drugs Controller General of India for conducting human trials of the Oxford-AstraZeneca Covid-19 vaccine candidate?

A. Serum Institute of India

B. National Institute of Epidemiology

C. AIIMS

D. Bharat Biotech

See answer ↓

8. Qdenga is a tetravalent dengue vaccine. Why must a dengue vaccine cover all four serotypes?

A. Infection with one serotype gives lasting protection only against that serotype, and a later infection by another can be more severe

B. A vaccine covering fewer serotypes would be rejected by CDSCO under the Drugs and Cosmetics Act

C. Each serotype attacks a different organ, so each needs its own dose schedule

D. The four serotypes are spread by four different mosquito species, so one vaccine cannot reach all of them

See answer ↓

9. Mandatory testing for Ethylene Glycol and Diethylene Glycol in oral liquid formulations was introduced through which regulatory instrument, effective October 2025?

A. IP 2026's first edition

B. Amendment List 09 to IP-2022

C. The Drugs and Cosmetics Rules, 1945

D. The National Pharmacy Commission Bill

See answer ↓

10. What does the Indian Pharmacopoeia Commission publish, which sets India's official drug-quality standards?

A. The Indian Pharmacopoeia

B. The Drug Price Control Order

C. The National Formulary of India

D. The Essential Drugs List

See answer ↓

11. In which year was the Indian Pharmacopoeia Committee constituted after independence?

A. 1946

B. 1955

C. 1948

D. 1951

See answer ↓

12. The NPPA currently caps prices on how many essential-medicine formulations, following the 2022 NLEM revision?

A. 48

B. 18

C. 935

D. 3,845

See answer ↓

13. Jan Aushadhi medicines are typically priced how much lower than comparable branded medicines?

A. 10-20%

B. 50-80%

C. 90-95%

D. 30-40%

See answer ↓

Answer Key

1. **B.** Statements 1 and 3 are correct. The order covers only medicines that mix both drugs. Single-drug medicines, like those with only phenylephrine, are not covered. The warning must be on the label, the leaflet and adverts. ↑ Q1
2. **A.** Chlorpheniramine is an antihistamine that eases runny nose and sneezing. Phenylephrine is a decongestant that opens a blocked nose. ↑ Q2
3. **C.** DTAB is set up under Section 5 of the Drugs and Cosmetics Act, 1940. The Director General of Health Services is its ex officio Chairman. The DCGI heads CDSCO and is a member of DTAB. ↑ Q3
4. **A.** Both are true, and R explains A. The 2018 ban of 328 FDCs and the 2024 ban of 156 FDCs both used Section 26A. ↑ Q4
5. **A.** The order is 3-1-2-4. 344 FDCs were banned in March 2016. 328 were banned in September 2018. 156 were banned in August 2024. The under-four warning was extended in August 2026. ↑ Q5
6. **B.** All such FDCs must now warn that they must not be used in children below four years of age. ↑ Q6
7. **A.** The answer is Serum Institute of India. It partnered with AstraZeneca to manufacture and trial the vaccine, later sold as Covishield. ↑ Q7
8. **A.** The right option says that one serotype gives lasting protection only against itself, and a later infection by another can be more severe. Dengue is caused by four related viruses, called serotypes. So a vaccine must protect against all four. Qdenga does this with a weakened dengue-2 backbone that carries genes from the other serotypes. The other options are wrong. All four serotypes spread through the same Aedes mosquito. No law demands four serotypes. And they do not target separate organs. ↑ Q8
9. **B.** Amendment List 09 to IP-2022, effective from 10 October 2025, mandated EG/DEG testing in all oral liquid formulations. ↑ Q9
10. **A.** IPC publishes the Indian Pharmacopoeia, India's official book of drug standards, setting identity, purity, strength, and quality benchmarks under the Drugs and Cosmetics Act, 1940. ↑ Q10

11. **C.**
    The correct answer is **1948**. The Indian Pharmacopoeia Committee was constituted in 1948, after independence.
    The first edition of the Indian Pharmacopoeia followed in 1955. So 1955 is the book, not the committee. 1946 falls before independence. 1951 is not a milestone in this history.
    Memory hook: committee 1948, first book 1955.
    ↑ Q11
12. **C.** The NPPA caps prices on 935 formulations, with average prices falling about 17% after the 2022 NLEM revision. ↑ Q12
13. **B.** Jan Aushadhi medicines are generally priced 50-80% lower than comparable branded medicines. ↑ Q13

Quick-check answers

1. **False.** ↑ 1
2. **True.** ↑ 2
3. **False.** ↑ 3
4. **False.** ↑ 4
5. **True.** ↑ 5

Previous year answers

1. **(c) Serum Institute of India** Serum Institute of India partnered with AstraZeneca to manufacture and trial the vaccine, later sold as Covishield.

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