

# Case Study: Role of the Drugs Technical Advisory Board (DTAB)

## About DTAB

- Constituted under **Section 5 of the Drugs and Cosmetics Act, 1940**.
  - Functions: To advise the Central Government and State Governments on technical matters relating to drugs and cosmetics.
  - Members: Includes Director General of Health Services (Chairperson), Drugs Controller General of India (DCGI), heads of central laboratories, pharmacology/medicine experts, and representatives from pharmacy/medical institutions.
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## Case Study: Ban on Fixed Dose Combinations (FDCs) in India (2016–2018)

### Background

- India has thousands of **Fixed Dose Combination (FDC)** drugs (medicines containing two or more active ingredients in a fixed ratio).
- Many FDCs were available without proper scientific evidence for safety/efficacy.
- Concerns: irrational prescriptions, antibiotic resistance, adverse reactions.

### DTAB's Role

1. **Evaluation**
    - The Ministry of Health sought advice from DTAB on the rationality of 344 FDCs.
    - DTAB reviewed data on safety, therapeutic justification, and global usage.
  2. **Recommendations**
    - DTAB recommended **banning irrational/unscientific FDCs** under Section 26A of the Act (in the interest of public health).
    - It advised that only those FDCs with adequate safety/efficacy evidence should continue.
  3. **Implementation**
    - Based on DTAB's advice, the Government banned 344 FDCs in 2016.
    - Pharmaceutical companies challenged the ban in the Delhi High Court.
  4. **Judicial Outcome**
    - Initially, the ban was stayed by the court.
    - Later, the Supreme Court (2017–2018) directed the DTAB to re-evaluate the drugs and provide expert recommendations.
    - After re-examination, many FDCs were permanently banned, while some were allowed with modifications.
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## Impact

- Ensured **patient safety** by removing irrational drugs from the market.
  - Strengthened regulatory framework by using **expert technical advice** rather than purely administrative action.
  - Highlighted DTAB's role as a **scientific advisory body** bridging government and judiciary.
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## Puzzle Questions:

- What is the crucial role in DTAB.
- FDC stands for Fixed \_\_\_\_\_ Combination.
- Section 26A?