Fixed Dose Combinations (FDCs)

Mains: *GS II – Governance, Health | GS III – Science and Technology*

Why in News?

Recently, Union Ministry of Health and Family Welfare has banned 16 Fixed-Dose Combination (FDC) drugs under Section 26A of the Drugs and Cosmetics Act, 1940.

What are Fixed Dose Combinations (FDCs)?

- **Definition –** Pharmaceutical formulation containing two or more active drugs in fixed proportions within a single, set-ratio dosage form (tablet, capsule, syrup, injection).
- **Purpose –** Designed to improve medication compliance by reducing pill burden and strategically combine for complementary drug effects to better manage complex or chronic conditions.

Why are FDCs used?

- **Patient Convenience –** Fewer pills reduce the burden on patient's adherence.
- **Therapeutic Synergy –** When drugs complement each other, effectiveness may improve.
- They are especially used in treatment of infections, diabetes, hypertension, pain management and chronic conditions like HIV and cardiovascular diseases.
- **Cost Efficiency –** It is cheaper than buying separate drugs.

Why are some FDCs being banned?

- **Irrational Combinations –** Many FDCs combine drugs with no proven medical benefit, it is better to be taken as single medicine.
    - ***Amoxicillin + Serratiopeptidase*** – Antibiotic with anti-inflammatory enzyme, no proven benefit together.
    - ***Dicyclomine + Paracetamol + Clidinium bromide*** – Unnecessary mix of antispasmodic and analgesic.
- **Increased Adverse Side Effects –** Combining multiple drugs increases the risk of negative drug interactions, toxicity, and unwanted side effects.
- **Antimicrobial Resistance –** Unjustified combinations of antibiotics can lead to drug resistance, making infections much harder to treat in the future.
- **Skin Care Risks –** Many banned FDCs are in the dermatology sector (e.g., mixing aloe vera with several vitamins and oils), which often lack scientific proof that the combination actually benefits the skin.

What is the institutional framework?

- **Drugs and Cosmetics Act, 1940 –** It is the foundational legislation in India that regulates the import, manufacture, distribution, and sale of drugs, cosmetics, and medical devices.
- **Drugs Technical Advisory Board (DTAB) –** Advises the central and state governments on matters related to the administration of the Act,
- Particularly regarding the therapeutic validity of FDC formulations.
- **Central Drugs Standard Control Organization (CDSCO) –** Functions as India's National Regulatory Authority (NRA) and is responsible for approving new drugs and monitoring clinical trials.

> ***Drugs and Cosmetics Act*** *provide the law, the* ***DTAB*** *provides the scientific evidence and recommendation, and the Central Government/CDSCO executes the official ban.*

What are the concerns for India?

- **Public Health –** Irrational FDCs compromise patient safety and treatment outcomes.
- **Antimicrobial Resistance –** India already faces high burden of drug-resistant infections and irrational antibiotics, worsen the crisis.
- **Poor Enforcement –** Companies often re-launch banned FDCs with minor changes; weak monitoring allows circulation.
- **Patient Awareness –** Many patients self-medicate, unaware of risks.

What are the government initiatives?

- **Ban on Irrational FDCs –** In a major crackdown, the Ministry of Health and Family Welfare (MoHFW) and the CDSCO banned irrational FDCs used for common ailments.
  - **2016 –** 344 FDCs banned.
  - **2018 –** 328 FDCs restricted.
  - **2024 –** 156 additional FDCs banned, including cough, cold, fever, pain medicines.
  - **2026 –** Latest crackdown on 16 FDCs, including antibiotics and skin formulations.
- **Strict Licensing Framework –** Through the Drugs and Cosmetics Act, the government mandates that any new FDC must undergo rigorous clinical trials and be scientifically proven safe before receiving marketing approval.
- **Expert Committee Reviews –** Under Supreme Court directives, the DTAB formed expert committees to systematically review and eliminate FDCs that pose risks.
- **Free Drugs Service Initiative (FDSI) –** Launched under the National Health Mission, this scheme promotes the prescription of essential generic medicines while proactively eliminating irrational and unscientific FDCs in public health facilities.
- **Awareness Campaigns –** Doctors advised patients to consult physicians for alternatives instead of discontinuing treatment abruptly.

What is the way forward?

- **Evidence-Based Regulation –** All FDCs must undergo rigorous clinical trials before approval.
- **Strengthen Enforcement –** Ensure banned drugs are not re-launched under new names.
- **Public Awareness –** Educate patients on dangers of irrational combinations and importance of consulting doctors.
- **Promote Rational Drug Use –** Encourage single-drug prescriptions or scientifically validated combinations.
- **Global Alignment –** Harmonize India's drug regulation with WHO and international best practices.
- **Antimicrobial Stewardship –** Integrate FDC bans into national strategy against antimicrobial resistance.

What are the ethical dimensions involved?

- **Autonomy & Informed Consent –** FDCs take away the prescriber's ability to adjust the dose of individual components.
- Patients may end up receiving a drug—and experiencing its side effects—that they did not strictly need, compromising their right to informed medical choice.
- **Beneficence vs. Maleficence –** The primary medical duty is to "do no harm."
- Combining drugs can cause unanticipated pharmacokinetic or pharmacodynamic interactions. Additionally, mismatched absorption rates can lead to under-dosing or overdosing of the active ingredients.
- **Public Health & Antimicrobial Resistance (AMR) –** Unnecessary or irrational combinations of antibiotics fuel the development of drug-resistant pathogens.
- This poses a global ethical threat, as creating resistant strains harms not only the individual patient but the broader community.
- **Exploitation & Cost –** Pharmaceutical companies may market "bad" or "ugly" FDCs to circumvent regulations, extend patents, or artificially inflate the cost of treatment.
- Patients bear the financial burden of paying for unnecessary additives.

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Reference

The Hindu | Fixed-Dose Combinations



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