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Combination (Fixed-Dose Combination) Drugs: Ban on 16 Irrational FDCs (2026) – Public Health, AMR and Drug Regulation

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Recent Developments:

- **The Ministry of Health and Family Welfare** has prohibited the **manufacture, sale and distribution of 16 Fixed-Dose Combination (FDC) drugs** under **Section 26A of the Drugs and Cosmetics Act, 1940** with immediate effect.
- **The ban follows the recommendations of an Expert Committee constituted by the Drugs Technical Advisory Board (DTAB)** after a **Supreme Court-directed review** of FDCs available in the market.
- **The prohibited FDCs were found to lack therapeutic justification, scientific evidence and favourable risk-benefit balance**, while some combinations were considered capable of aggravating **Antimicrobial Resistance (AMR)**.

Fixed-Dose Combination (FDC) Drugs:

- **A Fixed-Dose Combination (FDC)** is a pharmaceutical formulation containing **two or more Active Pharmaceutical Ingredients (APIs)** in a single dosage form such as a **tablet, capsule, syrup, injection or topical cream**.
- **FDCs are used** for treating **infectious diseases, diabetes, hypertension, cardiovascular disorders, pain, respiratory diseases and dermatological conditions**.
- **Properly designed FDCs** can improve **patient compliance, simplify treatment regimens, reduce pill burden and enhance therapeutic outcomes**.

Rational and Irrational FDCs:

- **A Rational FDC** combines medicines with **complementary mechanisms of action, compatible pharmacological properties and strong clinical evidence demonstrating superior benefit over separate administration**.
- **A Rational FDC** should also maintain **appropriate dose proportions, similar pharmacokinetic profiles and an acceptable safety profile**.
- **An Irrational FDC** combines drugs **without scientific justification, established therapeutic advantage or adequate clinical trial evidence**.
- **Irrational combinations** may expose patients to **unnecessary medicines, higher toxicity, adverse drug interactions and increased treatment costs**.

Regulatory Framework in India:

- **The Central Drugs Standard Control Organisation (CDSCO)** is India's **national drug regulatory authority** under the **Ministry of Health and Family Welfare**.
- **The Drug Controller General of India (DCGI)** functions under **CDSCO** and is responsible for **approval of new drugs, certain FDCs and clinical trials**.

Kamaraj IAS Academy
Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040
Phone: **044 4353 9988 / 98403 94477** / Whatsapp : **09710729833**

- **The Drugs and Cosmetics Act, 1940** and **Drugs and Cosmetics Rules** regulate the **approval, manufacture, import, sale and quality control of drugs** in India.
- **Section 26A of the Drugs and Cosmetics Act, 1940** empowers the **Central Government** to prohibit the manufacture, sale or distribution of drugs in the interest of public health.
- **New FDC approvals** require **scientific evaluation, safety data, efficacy evidence and regulatory clearance** before marketing.

Why were 16 FDC Drugs Banned?

- **The Expert Committee** concluded that these combinations **lacked therapeutic justification and sufficient scientific evidence**.
- **The risk associated with these combinations outweighed their expected clinical benefits**.
- **Several antibiotic combinations** were considered capable of **promoting irrational antibiotic use and accelerating Antimicrobial Resistance (AMR)**.
- **Certain dermatological combinations** containing **aloe vera and multiple herbal ingredients** lacked convincing evidence demonstrating superior efficacy over individual ingredients.

Illustrative Examples of Irrational FDCs:

- **Amoxicillin + Serratiopeptidase:**
- **Serratiopeptidase** is **acid-labile** and may be degraded before systemic absorption.
- **Clinical evidence does not establish additional therapeutic benefit** when combined with **amoxicillin**.
- **Major treatment guidelines do not recommend this combination**.
- **Norfloxacin + Tinidazole:**
- **Norfloxacin** primarily treats **bacterial infections**, whereas **Tinidazole** targets **protozoal infections**.
- **Simultaneous bacterial and protozoal infections are uncommon**, making routine combined use scientifically unjustified.
- **Amoxicillin + Clavulanic Acid:**
- **Clavulanic acid** inhibits **beta-lactamase enzymes** produced by resistant bacteria.
- **Its indiscriminate use** in infections without resistant organisms **unnecessarily increases antibiotic exposure and contributes to AMR**.

Antimicrobial Resistance (AMR):

- **Antimicrobial Resistance (AMR)** occurs when **bacteria, viruses, fungi or parasites evolve resistance**, making antimicrobial medicines ineffective.
- **Irrational antibiotic combinations** increase **selective pressure**, enabling resistant microorganisms to survive and proliferate.
- **AMR** increases **treatment failure, prolonged illness, healthcare expenditure, mortality and the need for expensive reserve antibiotics**.
- **Preserving the effectiveness of existing antibiotics** is a critical component of **global public health policy**.

Concerns with Dermatological FDCs:

- **Many dermatological FDCs** combine **aloe vera, Vitamin E, jojoba oil, olive oil, tea tree oil and other herbal ingredients** without robust comparative evidence.
- **Long market availability alone does not establish scientific validity or clinical superiority**.
- **Steroid-antifungal combinations** may suppress local immune responses, **mask fungal infections and facilitate persistent or resistant infections**.

Risks Associated with Irrational FDCs:

- **Patients may experience unnecessary adverse drug reactions and allergic responses** because of additional ingredients.
- **Fixed-dose formulations limit dose flexibility**, preventing independent adjustment of individual medicines.
- **Unnecessary exposure to antibiotics increases antimicrobial resistance and compromises future treatment options**.
- **Irrational FDCs may delay accurate diagnosis by masking disease progression while increasing treatment costs**.

Measures to Promote Rational Drug Use:

- **Doctors** should prescribe **evidence-based medicines supported by high-quality clinical studies**.
- **Pharmacists** should remain updated regarding **banned FDCs and promote rational dispensing practices**.
- **Patients** should avoid assuming that medicines containing multiple ingredients are automatically superior.
- **Health authorities** should strengthen **pharmacovigilance, antimicrobial stewardship programmes, prescription audits and public awareness campaigns**.
- **Periodic scientific review of marketed FDCs** should continue to eliminate irrational formulations.

Related Institutions and Committees:

- **Central Drugs Standard Control Organisation (CDSCO)** regulates drug approval and quality standards.
- **Drug Controller General of India (DCGI)** approves new drugs and many FDCs.
- **Drugs Technical Advisory Board (DTAB)** is the highest statutory technical advisory body on drugs.
- **Indian Council of Medical Research (ICMR)** provides scientific guidance on public health issues including **AMR**.
- **National Centre for Disease Control (NCDC)** coordinates surveillance and national action against **AMR**.

UPSC Value Addition:

Important Provisions:

- **Section 26A, Drugs and Cosmetics Act, 1940** empowers the Central Government to prohibit drugs in public interest.
- **DTAB** is the highest statutory technical advisory body constituted under the **Drugs and Cosmetics Act, 1940**.
- **CDSCO** functions under the **Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare**.
- **DCGI** heads **CDSCO** and oversees approvals for new drugs, clinical trials and specified FDCs.

Exam-Relevant Concepts:

- **Active Pharmaceutical Ingredient (API):** The biologically active substance responsible for the therapeutic effect of a medicine.
- **Antimicrobial Stewardship:** Coordinated interventions that promote appropriate antimicrobial use to improve patient outcomes while reducing resistance.
- **Pharmacovigilance:** Continuous monitoring, assessment and prevention of adverse effects associated with medicines after their approval.
- **Evidence-Based Medicine (EBM):** Clinical decision-making based on the best available scientific evidence, physician expertise and patient needs.

Beta-Lactamase Inhibitors: Agents such as **clavulanic acid** that protect certain antibiotics by inhibiting bacterial enzymes responsible for antibiotic degradation