Daily Mains Practice Question 27-06-2026

GS III - Health

What are Fixed Dose Combinations (FDCs)? Discuss their advantages and concerns associated with irrational FDCs in India & the measures taken by the Government to regulate them. ***(15 marks, 250 words).***

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Answer

Introduction:

A Fixed Dose Combination (FDC) is a pharmaceutical product containing two or more active pharmaceutical ingredients (APIs) in a fixed ratio within a single dosage form. While rational FDCs improve therapeutic outcomes, the widespread availability of irrational FDCs has emerged as a major public health concern in India.

Main Body

Advantages of Rational FDCs

- **Improved Patient Compliance** – Reduces pill burden, improving adherence in chronic diseases.
- **Therapeutic Synergy** – Complementary drugs enhance efficacy (e.g., TB, HIV, hypertension).
- **Reduced Antimicrobial Resistance** – Ensures patients receive complete multidrug therapy, reducing resistance in diseases like TB.
- **Cost Efficiency** – Single formulation lowers manufacturing, packaging and treatment costs.
- **Convenience** – Simplifies prescribing, dispensing and public health logistics.
- **Reduced Medication Errors** – Fewer tablets reduce chances of missed or incorrect doses.

Concerns Associated with Irrational FDCs

- **Lack of Scientific Evidence** – Many combinations lack adequate clinical trials proving safety and efficacy.

    - **Example:** Amoxicillin + Serratiopeptidase – Antibiotic with anti-inflammatory enzyme, no proven benefit together.
- **Increased Adverse Drug Reactions** – Unnecessary drug combinations expose patients to greater risk of toxicity, drug interactions and side effects & also difficulty in identifying the offending drug.
- **Antimicrobial Resistance (AMR)** – Irrational antibiotic combinations promote indiscriminate antibiotic use which weakens India's National Action Plan on AMR.
- **Inappropriate Dosage Ratios** – Fixed doses may not suit patients of different ages, weights, or disease severity.
- **Unnecessary Financial Burden** – Patients pay for medicines containing ingredients they may not require.
- **Regulatory Loopholes** – States licensed several FDCs without prior approval from the Central Drugs Standard Control Organization, leading to thousands of unapproved products entering the market.
- **Ethical Concerns** – They undermine individualized therapy, favour marketing over evidence, and breach the principle of "Do No Harm" (non-maleficence).

Government Measures to Regulate Irrational FDCs

- **Ban on Irrational FDCs** – The Central Government has prohibited hundreds of irrational FDCs in phases under the provisions of the Drugs and Cosmetics Act after expert committee recommendations.
- **Strengthening Central Approval** – New FDCs require approval under the provisions of the New Drugs and Clinical Trials Rules, 2019 before manufacture.
- **Expert Committee Reviews** – Committees such as the Kokate Committee reviewed thousands of marketed FDCs for safety, efficacy, and therapeutic justification.
- **Strict Licensing** – Mandatory clinical evidence and safety data before granting marketing approval for new FDCs.
- **Regulatory Coordination** – Improved coordination between CDSCO and State Drug Controllers to prevent licensing of unapproved FDCs.
- **Digital Drug Regulation** – Online drug approval and licensing systems have improved regulatory oversight and transparency.

Conclusion:

Rational FDCs improve treatment adherence, affordability, and therapeutic outcomes, while irrational FDCs endanger patient safety and accelerate antimicrobial resistance. Ensuring evidence-based approvals, strict regulation, robust pharmaco-vigilance, and rational prescribing is essential for their safe and effective use.

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