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# Daily Mains Answer Writing

## *(Day - 29)*

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# What do you understand by Fixed-Dose drug Combinations (FDCs)? Discuss their issues and challenges associated with them in India.

- An FDC is a cocktail of two or more active drug ingredients in a fixed ratio of doses. According to IMS Health, almost half the drugs sold in India in 2018 were FDC, making it a world leader in combination drugs.
- As of April, the CDSCO had approved 1,288 FDCs. This is disproportionately high compared with the availability in a tightly regulated market like USFDA, which has only a few hundred approved FDCs.
- Given the widespread usage, there is no doubt that FDC's benefits are unparalleled in ways such as –
    - Efficiency and Efficacy: FDCs' popularity in India is due to advantages such as increased efficacy, better compliance, reduced cost and simpler logistics of distribution.
    - Lifesaving drugs: FDCs have shown to be particularly useful in the treatment of infectious diseases like HIV, malaria and tuberculosis, where giving multiple antimicrobial agents is the norm. FDCs are also useful for chronic conditions especially, when multiple disorders co-exist.
- However, the reason behind why FDC's are tightly regulated in foreign market is because of the Issues and challenges associated with it –
    - Poor regulation: According to a study, of the 110 anti-TB FDCs available in India, only 32 (less than 30%) have been approved by the Central Drugs Standard Control Organisation (CDSCO), the country's drug regulator.
    - Redundant Approval Process of CDSCO - Main amongst them are institutional problems such as understaffing, lack of skills, and inadequate infrastructure. However, the most significant issue is the issuance of manufacturing licenses by the State Licensing Authority without the prior clearance of the Drug Controller General of India DCG(I).
    - Dangerous to human health: The FDCs formulated without due diligence can pose problems namely pharmacodynamic mismatch. One drug having additive/ antagonistic effect leading to reduced efficacy or enhanced toxicity and chemical no compatibility leading to decreased shelf life.
    - No therapeutic justification: The Health ministry banned 344 FDC's after the Drugs Technical Advisory Board recommended that there is no therapeutic justification; and involve risk to human beings;.
    - Problem of plenty: The estimated number of FDCs in India is over 6000.The existence of unlimited brands of FDCs with different permutations and combinations leads to confusion rather than guiding the prescribing doctor.
- Today need of the hour is to curb the irrational use of FDC's which require multistep approach such as –
    - Involving all stakeholders - consumers, physicians, regulatory authority, industry, and the academicians, is needed.
    - Pharmaceutical companies shall be forced to uphold the ethical concepts while introducing an FDC product. They have to conduct detailed studies on such combinations.
    - All the new and existing FDC products shall be subjected to a closely monitored national level post-marketing studies (Phase IV) involving identified community and hospital pharmacies in the country.
    - The marketing approval for the new FDC shall be given by the DCGI only after subjecting for Pharmacoeconomic and pharmacovigilance studies for a specified period of time.
    - The enforcement mechanism by the regulators needs to be strengthened. Both the central and state regulators must harmonize their procedures for licensing FDCs.
    - Awareness generation over irrational use of FDCs must be enhanced to combat anti biotic resistance.