



Mains Practice Question

Q. What do you understand by fixed dose combination(FDC) drugs? Highlight the advantages and limitations of FDCs in addressing the health care in India. (250 words)

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Approach

- Describe FDCs.
- State the limitations of FDCs and consequential limitation in addressing health care in India.
- Give conclusion.

Introduction:

More than one drug is frequently used for treatment of either single ailment or multiple conditions. Sometimes, two or more drugs are combined in a fixed ratio into a single dosage form, which is termed as fixed dose combinations (FDCs).

Body

Limitation of FDC in addressing the health care in India

- **Cost:** FDCs are sometimes more expensive than separate tablets.
- **Drug Interactions:** Potential quality problems when drugs are combined, drug interactions may lead to alteration of the therapeutic effect.
- **Inflexibility:** If a patient is allergic or has a side-effect to one of component, the FDC must be stopped and replaced by separate tablets. Dosing is inflexible and cannot easily be regulated to patient's needs (each patient has unique characteristics such as weight, age, pharmacogenetics, co-morbidity, that may alter drug metabolism and effect). This criticism does not, however, apply to TB or HIV/AIDS where FDCs are made with weight-adjusted dosages.
- **Lower shelf life:** Chemical non-compatibility leading to decreased shelf life.
- **Combinations without rational basis:** The FDC formulation may have up to 5 or even more ingredients with or without rationality of their presence and in the quantity. The committee under the chairmanship of C.K. Kokate, examined the safety and efficacy of unapproved FDCs. The committee evaluated 418 FDCs, out of which 324 FDCs were found to be irrational.
- **No therapeutic justification:** The Health ministry banned 344 FDC's after the Drugs Technical Advisory Board recommended that "there is no therapeutic justification" for the ingredients contained in the banned FDC drugs and that these medicines "may involve risk to human beings".
- **Problem of plenty:** The estimated number of FDCs in India is over 6000. Time and again, studies, editorials have shown violation of scientific merits in having many FDCs without adequate justification. Exploiting the liberal licensing system, many times, bizarre FDCs find place. The existence of unlimited brands of FDCs with different permutations and combinations leads to confusion rather than guiding the prescribing doctor.

Conclusion:

- To curb the irrational use of FDC in India, a multistep approach involving all stakeholders, for

- example, consumers, physicians, regulatory authority, industry, and the academicians, is needed.
- The enforcement mechanism by the regulators needs to be strengthened. Both the central and state regulators must harmonize their procedures for licensing FDCs.

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