Panel Finds Dosing Mismatches in Many FDCs

The Drug Technical Advisory Board (DTAB) sub-committee has found that many Fixed-Dose Combinations (FDCs) were formulated without due diligence, with dosing mismatches that could result in toxicity.

- It found that most pharma companies had not generated the "safety and efficacy data" of their own FDCs. The published literature they submitted to justify the FDC was not relevant to India and relied on a few biased studies.
- According to the sub-committee, of the 349 FDCs under review, 343 of them must be banned.

Consequences of Dose Mismatch

- In FDCs where there is a dosage mismatch among the ingredients, it would result in toxicity or contrarily lack of any effect on the patient.
- For most FDCs, their use would lead to unnecessary overuse, and the patients would be exposed to risk of multiple ingredients when one would suffice.

Background

- In 2017, the Parliamentary Standing Committee on Health and Family Welfare had observed that some state licensing authorities had issued manufacturing licences for several FDCs without prior clearance from Central Drugs Standard Control Organization (CDSCO). This had resulted in availability of many FDCs, which have not been tested for efficacy and safety, putting patients at risk.
- CDSCO had earlier banned the use of 349 FDCs, against which the pharma companies had moved various courts.
- Finally the Supreme Court in its judgment in had referred the matter to DTAB for a fresh review on whether these drugs should continue to be marketed. Pursuant to this the Drug Technical Advisory Board (DTAB) had appointed a sub-committee to relook at FDCs and give its recommendations.

Fixed Dose Combination (FDC) Drugs

- A FDC drug is basically a combination of two or more drugs.
- The basic rationale of making “fixed dose combination” medicinal products is either to improve patient compliance or to benefit from the synergistic effects of the two medicinal products given together.

Central Drugs Standard Control Organization (CDSCO)

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.
- Major Functions:
    - Regulatory control over the import of drugs, approval of new drugs and clinical trials.
    - Approval of certain licences as Central Licence Approving Authority.