Recently, the government has prohibited the manufacture for sale, sale or distribution for human use of 328 FDCs and restricted the manufacture, sale or distribution of six FDCs in India.

**WHY IN NEWS?**

An FDC is a cocktail of two or more therapeutic drugs packed in a single dose e.g. in the form of tablets, capsules, syrups, powders etc. The main advantages of FDCs are increased efficacy, less adverse effects, availability of a single medicine for treating multiple symptoms.

**FDC 2015**

- Chandrashekhar Subramanian Committee recommended banning 349 FDCs, claiming they were "unsafe" and "irrational" for consumption.

**2016**

- Government banned them under Section 26 A of the Drugs and Cosmetics Act, 1940. That was challenged in High Courts and Supreme Courts.

**2017**

- As per the direction of Supreme Court, Nilima Shiragar Committee was formed to review the safety, efficacy and therapeutic justification of 344 FDCs.

**BACKGROUND**

Continuation of the ban of unapproved formulation i.e. mismatch of dosage could result in toxicity.

Irrelevant data, relied on biased studies, failed to prove safety, rationality and compatibility of these FDCs.

Wrong dosage of unsafe combination drugs can make the human body resistant to treatment.

India has become a "dumping ground" for irrational FDCs, disapproved in other countries for consumption.

No therapeutic justification for the ingredients contained in 328 FDCs.

**STATE DRUG AUTHORITIES**

- State Drug Authorities are the licensing authorities for marketing drugs.
- Central Drugs Standard Control Organization (CDSCO), works under the Ministry of Health and Family Welfare, is the Country’s Drug Regulator. It approves new drugs for manufacture and import.
- Drugs Technological Advisory Board plays a key role in giving technical approvals for new drugs.

**ISSUES**

- FDCs are not covered under the ambit of price control regime.
- An opaque regulatory framework and ambiguity over licensing powers; India has approved more than 1000 FDCs, whereas WHO mentions only 24 FDCs and USFDA has only a few 100 approved FDCs.

- It being cheaper gives scope of misuse to pharma companies to combine existing active ingredients to make new products rather than discover new medicines.

**IMPACT**

- Market size of the banned drugs is estimated to be around Rs 10-12 billion and will impact the country’s top drug makers.

**DRUG REGIME IN INDIA**

- The Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic Rules, 1945.
- The Drugs Technical Advisory Board constituted under the Drugs and Cosmetic Act, 1940.
- The Drugs Regulatory Authority of India (DRUGS) and Central Drugs Standard Control Organization (CDSCO).
- The Drugs Acts and Rules provide a framework to control the manufacture, sales and distribution of FDCs.