Fixed-dose combination drugs (FDCs)

Prelims – *General Science| Current events of National Importance*

Mains (GS II) – *Issues relating to development and management of Social Sector/Services relating to Health.*

Why in news?

The Central Drugs Standard Control Organisation (CDSCO) has recently prohibited the manufacture, sale, and distribution of 35 FDCs that were authorized by drug regulators across all States and Union Territories, citing the lack of prior safety and efficacy assessments.

- **Fixed-dose combination drugs –** FDC drugs are those which contain a combination of *two or more Active Pharmaceutical Ingredients (APIs)* in a fixed ratio.

  Active Pharmaceutical Ingredients (APIs) *is the biologically active component of a drug product (tablet, capsule, cream, injectable) that produces the intended effects.*

- FDC drugs are widely used in the treatment of tuberculosis, Diabetes and as painkillers and nutrition supplements.
- **Advantages of FDC drugs**
  - Increased patient acceptance
  - Increased health worker compliance
  - Easier drug management
  - Lower risk of misuse of single drugs
  - Lower risk of emergence of drug resistance
- **Regulation of FDC** – In India FDC are regulated by CDSCO as per the provision of NDCT (New Drugs and Clinical Trials Rules) Rules 2019 under the ***Drugs and Cosmetics Act 1940.***
- As per the Drugs and Cosmetics Act 1940, ***FDCs that Combined for the first time in a fixed ratio are classifies as New Drugs*** and it requires evaluation of safety and efficacy by CDSCO.

The Central Drugs Standard Control Organisation (CDSCO)

• **CDSCO** - The Central Drugs Standard Control Organisation (CDSCO) is India's national regulatory body for ***pharmaceuticals and medical devices*** under the Drugs and Cosmetics Act, 1940
• **Headed by –** Drugs Controller General of India (DCGI)
• It functions under the *Ministry of Health and Family Welfare*.
• **Zonal Offices** - CDSCO has 6 zonal offices of at Mumbai, Kolkata, Chennai, and Ghaziabad, Hyderabad, Ahmedabad.
• **Functions -** CDSCO is responsible for discharging functions assigned to the Central Government under the ***Drugs and Cosmetics Act - 1945***.
- Approval of new drugs and novel drug formulations including Fixed-Dose Combinations (FDCs)
- Oversight of clinical trials conducted in India.
- Quality control of imported drugs and medical devices.
- Coordination with State Drug Control Organizations to ensure uniform enforcement of regulations.

References

1. The Hindu| Govt bans 35 fixed-dose combination drugs
2. CDSCO| Central Drugs Standard Control Organisation

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