Government Bans 14 Combination Drugs

Why in News?

The Central Government of **India has issued a gazette notification banning 14 fixed-dose combination (FDC) medicines** commonly used to treat cough, fever, and infections.

- The ban, which takes immediate effect, follows recommendations from an expert committee appointed to assess the efficacy of these drug combinations.

What are FDC Medicines?

- **Definition:**
  - According to the Central Drugs Standard Control Organisation (CDSCO), FDCs refer to products **containing one or more active ingredients used for a particular indication(s).**
- **Reason for the Ban:**
  - The ban follows the **recommendations of the expert committee and the Drugs Technical Advisory Board.**
  - The committee concluded that the banned FDCs lack therapeutic relevance and may pose risks to human beings.

What are the Challenges of FDC?

- **Increased Risk of Side Effects:**
  - Combining multiple active ingredients in FDC drugs **can lead to a higher risk of adverse drug interactions and increased susceptibility to side effects.**
  - Some patients **may experience heightened sensitivity or allergic reactions** to one or more components of the FDC drug, which may be difficult to identify and manage due to the fixed combination.
  - For example, A combination of Paracetamol, Bromhexine, Phenylephrine, Chlorpheniramine, and Guaiphenesin in a single FDC drug may increase the risk of side effects such as drowsiness, dizziness, and elevated blood pressure.
- **Regulatory Challenges:**
  - Regulating FDC drugs can be challenging due to the **complexities associated with evaluating the safety and efficacy** of multiple active ingredients in a single formulation.
  - Ensuring quality control and standardization of FDC drugs becomes more demanding as compared to single-component medications.
- **Overuse and Misuse:**
  - FDC drugs can contribute to overuse and misuse of medications. Patients may unknowingly consume multiple active ingredients unnecessarily or in inappropriate combinations, leading to potential health risks.
- **Lack of Evidence-based Clinical Data:**
  - Some FDC drugs may have been approved based on limited or insufficient clinical evidence supporting their efficacy and safety profiles.
  - The absence of robust scientific data can raise concerns about the appropriateness and reliability of FDC drugs for specific medical conditions.

What is the Central Drugs Standard Control Organisation (CDSCO)?

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act 1940.
- **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
- **Drug Controller General of India (DCGI)**
  - DCGI is responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India.
  - It comes under the Ministry of Health & Family Welfare.

Source: TH