FIXED DOSE COMBINATIONS

WHY IN NEWS?

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.

FDC

An FDC is **a cocktail of two or more therapeutic drugs** packed in a single dose e.g. cough syrups, painkillers, dermatological drugs etc. It has **specific advantages** e.g. increased efficacy, less adverse effects, easily available, cheaper as one FDC medicine can treat multiple illness symptoms.

BACKGROUND

2015 – Chandra kant Kokate 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 Shirsagar Committee** was formed to review the safety, efficacy and therapeutic justification of 344 FDCs. It recommended –

- Continuation of the **ban**
- 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 FDC.
- Wrong dosage of **unsafe combination drugs** can make 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.

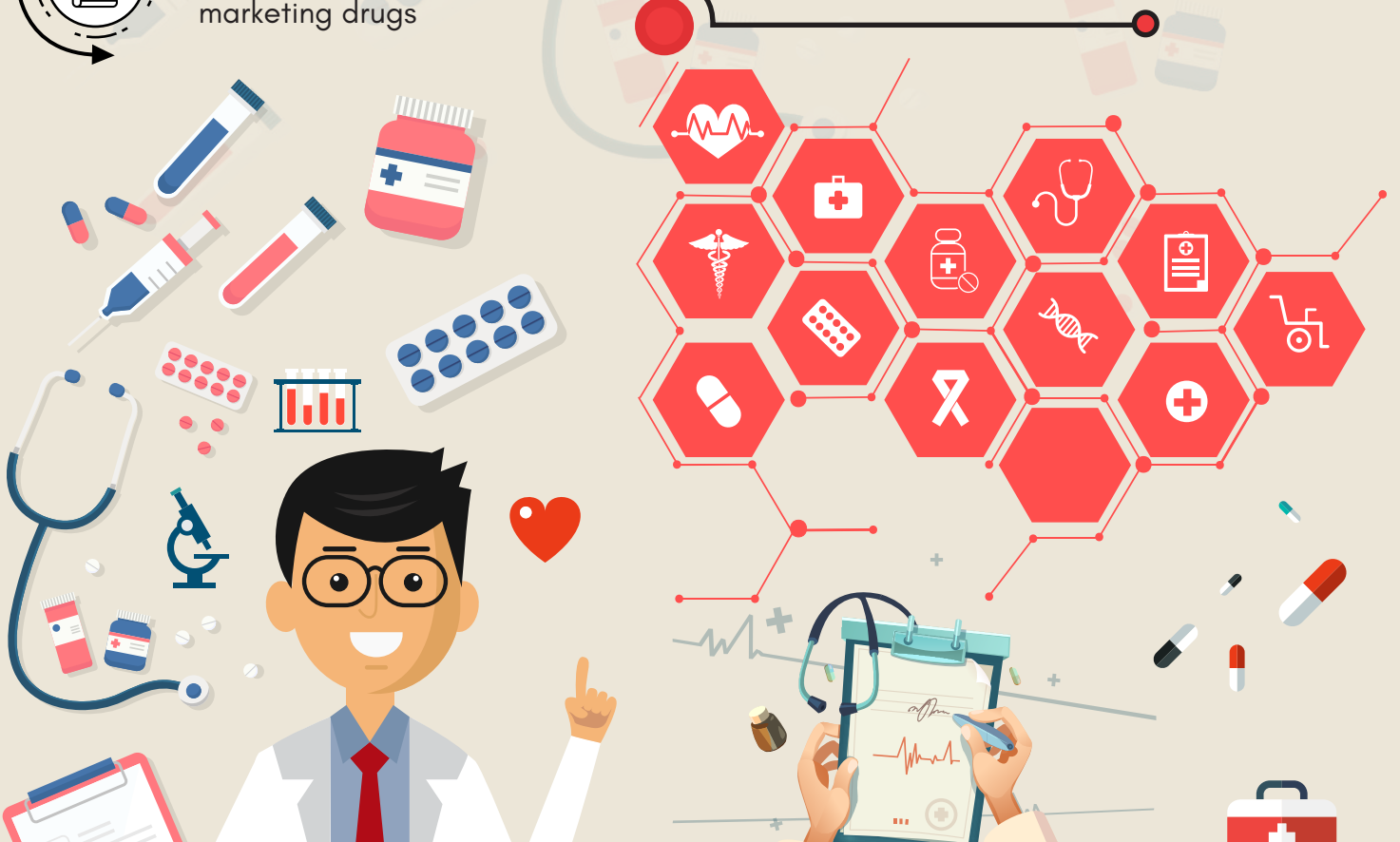
DRUG REGIME IN INDIA

Drugs are regulated by the **Drugs and Cosmetics Act, 1940** and **Drugs and Cosmetic Rules, 1945.**

Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940 is the highest statutory decision-making body on technical matters.

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.

State Drug Authorities are the licensing authorities for marketing drugs



ISSUES

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.

FDCs are not covered under the ambit of price control regime.

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

IMPACT

VISIONIAS INSPIRING INNOVATION

Market size of the banned drugs is estimated to be around Rs 20-22 billion and will impact the country's top drug makers.