Regulatory Framework for Over-The-Counter (OTC) Drugs

Prelims *– Current Events of National Importance*

GS II *– Health | Human Resource*

Why in News?

India may soon have a streamlined regulatory framework around OTC drugs as the Central Drugs Standard Control Organisation (CDSCO) has approved the recommendations made by a special OTC sub-committee.

Over-the-counter (OTC) Drugs
• It is also known as nonprescription medicines, are pharmaceuticals that can be purchased without a prescription from a healthcare professional. • These medications are generally considered safe and effective when used as directed on the label. • This includes medications that are part of the National List of Essential Medicines (NLEM) and are approved for distribution by the CDSCO. • Typically, drugs like analgesics, antiseptics, contraceptives, some vitamins, laxatives, cough syrups, etc. are dispensed as OTC. • The duration for which these medicines can be used has been kept low to avoid misuse.

- **Recommendations -** The committee draw up a framework for OTC drugs, and also create a mechanism to determine which medicines can qualify as OTC.
- Around 27-30 drugs, primarily analgesics, topical ointments for pain, cough-and-cold medications, etc., could be part of India's first comprehensive OTC drugs list. More drugs can be added in future.
- The framework and guidelines can be formalized once it gets approval from the health ministry.
- **Health concerns** - Self-medication with drugs such as antibiotics, painkillers, and sedatives, commonly bought from chemists without a prescription, can lead to significant health risks and side effects.
- Antibiotics like amoxicillin, ciprofloxacin, and azithromycin are frequently used without medical guidance. Improper or incomplete use of antibiotics can lead to antibiotic resistance, making future infections harder to treat and spreading resistant bacteria in the community.
- Painkillers, especially Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) like ibuprofen, diclofenac, and naproxen are also commonly misused.
    - It can irritate the stomach lining, leading to ulcers and bleeding, and in some cases cause kidney damage or raise the risk of heart attack and stroke.

Prescription drugs are categorized into Schedules H, H1, and X of the Drugs Rules, 1945.

- **Advantage -** Experts have cautioned against self-medication across categories, and, therefore, having a clear list of OTC medications will help reduce misuse.
- **Disadvantage for pharma sector -** Clampdown on OTC drug sales could dent Indian Pharma Market (IPM) volume growth, especially in the acute therapy segment where self-medication is rampant in analgesics, antipyretics, and common cold medicines.

Reference

Business Standard | Regulatory framework for OTC drugs

