Central Drugs Standard Control Organization (CDSCO)

Overview:

- CDSCO is the national regulatory authority for drugs and cosmetics in India.
- It functions under the Ministry of Health and Family Welfare, Government of India.
- The organization operates under the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945.
- **Headquarters:** New Delhi
- **Headed by:** Drugs Controller General of India (DCGI)

Main Functions of CDSCO:

A. Regulation of Drugs and Cosmetics

- Approves **new drugs** before they can be marketed in India.
- Regulates **clinical trials**.
- Controls **import and export** of drugs.
- Approves and monitors **biological products** (vaccines, blood products).

B. Licensing

- Issues licenses for manufacturing/import of:
  - New drugs
  - Blood products
  - Vaccines
  - Large-volume parenterals (LVPs)
- Coordinates with **State Drug Regulatory Authorities**.

C. Quality Control

- Ensures quality and safety through post-marketing surveillance, inspections, and lab testing.

D. Pharmacovigilance

- Collaborates with Indian Pharmacopoeia Commission (IPC) and hospitals to monitor Adverse Drug Reactions (ADRs).

E. Medical Devices Regulation

- Regulates manufacture, import, sale, and labeling of medical devices.

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F. Schedule Drugs and Rules

- Defines and updates Schedules (like Schedule H, H1, X) for drug classification.

Divisional Structure:

- CDSCO is divided into various zonal, sub-zonal, and port offices for better enforcement:
  - 7 Zonal Offices
  - 4 Sub-Zonal Offices
  - 13 Port Offices
  - Central Labs like:
    - Central Drugs Laboratory (CDL), Kolkata
    - Regional Drug Testing Laboratories (RDTLs)

Indian Pharmacopoeia Commission (IPC)

Overview:

- IPC is an autonomous institution under the Ministry of Health and Family Welfare, Government of India.
- It is responsible for preparing the Indian Pharmacopoeia (IP) — the official book of standards for drugs in India.
- **Headquarters:** Ghaziabad, Uttar Pradesh

Main Functions of IPC:

A. Publication of Indian Pharmacopoeia

- Sets **quality standards** for:
  - Active pharmaceutical ingredients (APIs)
  - Finished pharmaceutical products
  - Excipients, antibiotics, vaccines, herbal products
- Ensures **safety, efficacy, and quality** of drugs manufactured and sold in India.

B. National Coordination Centre for Pharmacovigilance Programme of India (PvPI)

- IPC manages **PvPI**, which collects and analyzes data on **adverse drug reactions (ADRs)**.
- Promotes **drug safety** by reporting side effects from hospitals, healthcare providers, and pharma companies.

C. Monographs and General Chapters

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- Publishes **monographs** for drugs and general test procedures (e.g., identity, purity, strength).
- These standards are legally enforceable.

D. Reference Standards

- Develops and distributes **Indian Pharmacopoeial Reference Standards (IPRS)** to labs and industries.

E. Training and Collaboration

- Conducts **workshops, training sessions**, and research to improve pharmaceutical standards and regulatory awareness.

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