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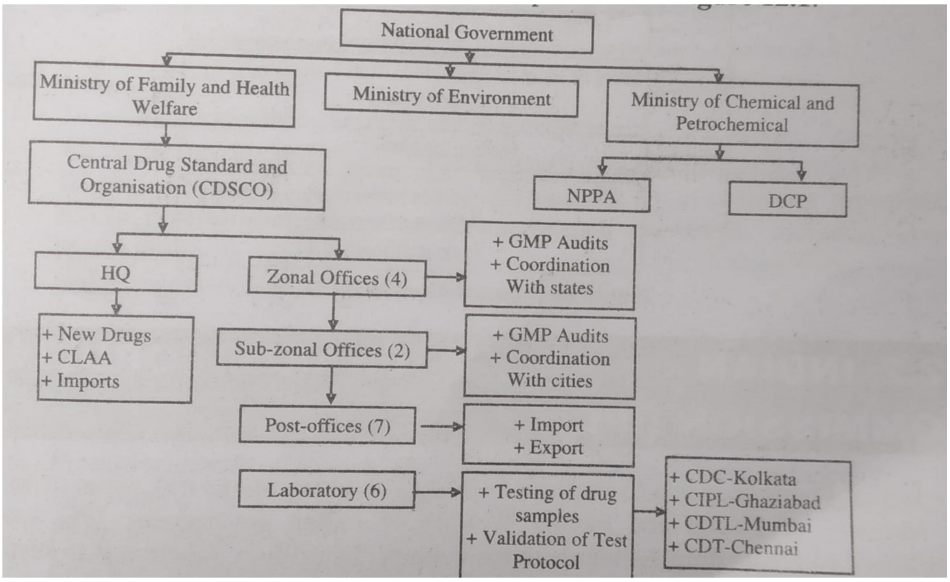
Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 12 : Government Pharma Regulator Bodies

Chapter 12
Government Pharma Regulator Bodies

Central Drugs Standers Control Organization (CDSCO)

- They Control and Regulates Drug related matters at National and International Level , and also cooperate the State Drugs Controllers
- The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.
- The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
- Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

Structure



Functions and Roles of CDSCO

- ✓ It makes policies and procedures for uniform implementation of the provision s of Drugs and Cosmetics Act and Rules.
- ✓ It Sets Standards for drugs and Cosmetics and medical Devices.
- ✓ It Controls the import of Drugs , approval of new drugs and clinical trials.
- ✓ It acts as license Providing Authority for approval of certain Licences . like license for import of drugs , blood bank.
- ✓ it checks the quality of imported drugs through the port offices.
- ✓ It maintains drugs testing laboratories for sample testing.
- ✓ Amendment of D and C Act and rules.
- ✓ It Bans Drugs and cosmetics.
- ✓ It Conducts Meetings with International Organizations like WHO , US FDA , European Medical Devices Agency of Japan etc.
- ✓ It grant Test license for Drugs.

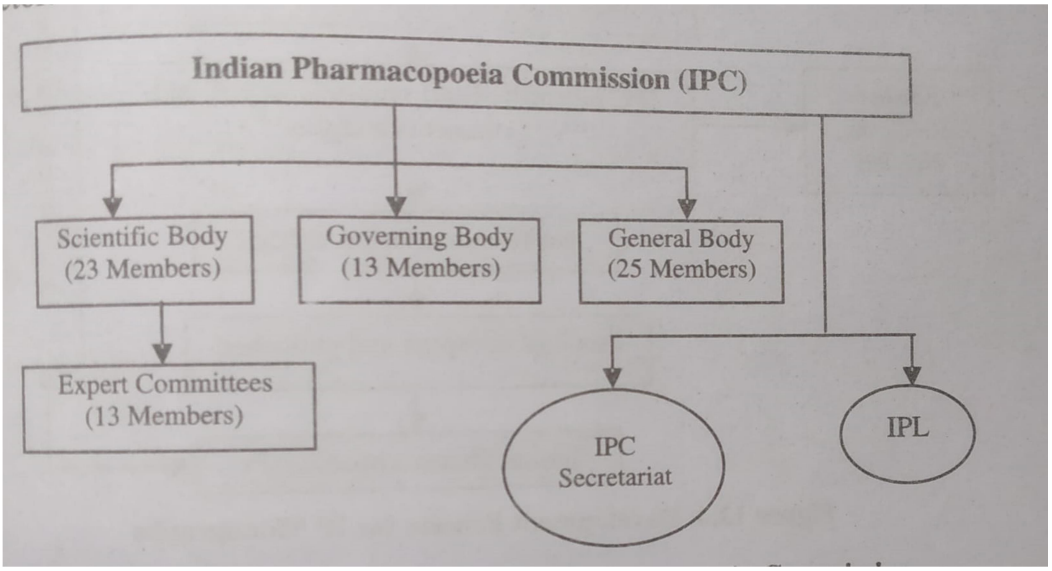
Indian Pharmacopoeia Commission (IPC)

- ➢ Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India.
- ➢ The set of standards are published under the title Indian Pharmacopoeia (IP) which has been modelled on and historically follows from the British Pharmacopoeia.

Vision

- → To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis

Structure



Function of IPC

- It issues Official Documentation in the form of IP.
- It improves the quality of Drugs by adding the new monographs and updates old monographs.
- It publishes National Formulary of India.
- It conducts Meetings with national and international institutions for better performance.
- Planning esucation programmes, skill development initiatives, and research activities.

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