Chapter-13

Role of all the government pharma regulator bodies

Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)

Role of all the government pharma regulator bodies:

- Regulatory authorities act as a guardian that ensures the safety, efficacy and quality of drugs available to the public, to identify the strengths and weaknesses of drug regulation and to propose strategies to improve drug regulation.
- They also play a vital role to ensure and increase regulatory implementation in non-regulated parts of the world for safety of people residing there.

Major Regulatory Agencies World Wide

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products.

Country	Name of Regulatory Authority
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)

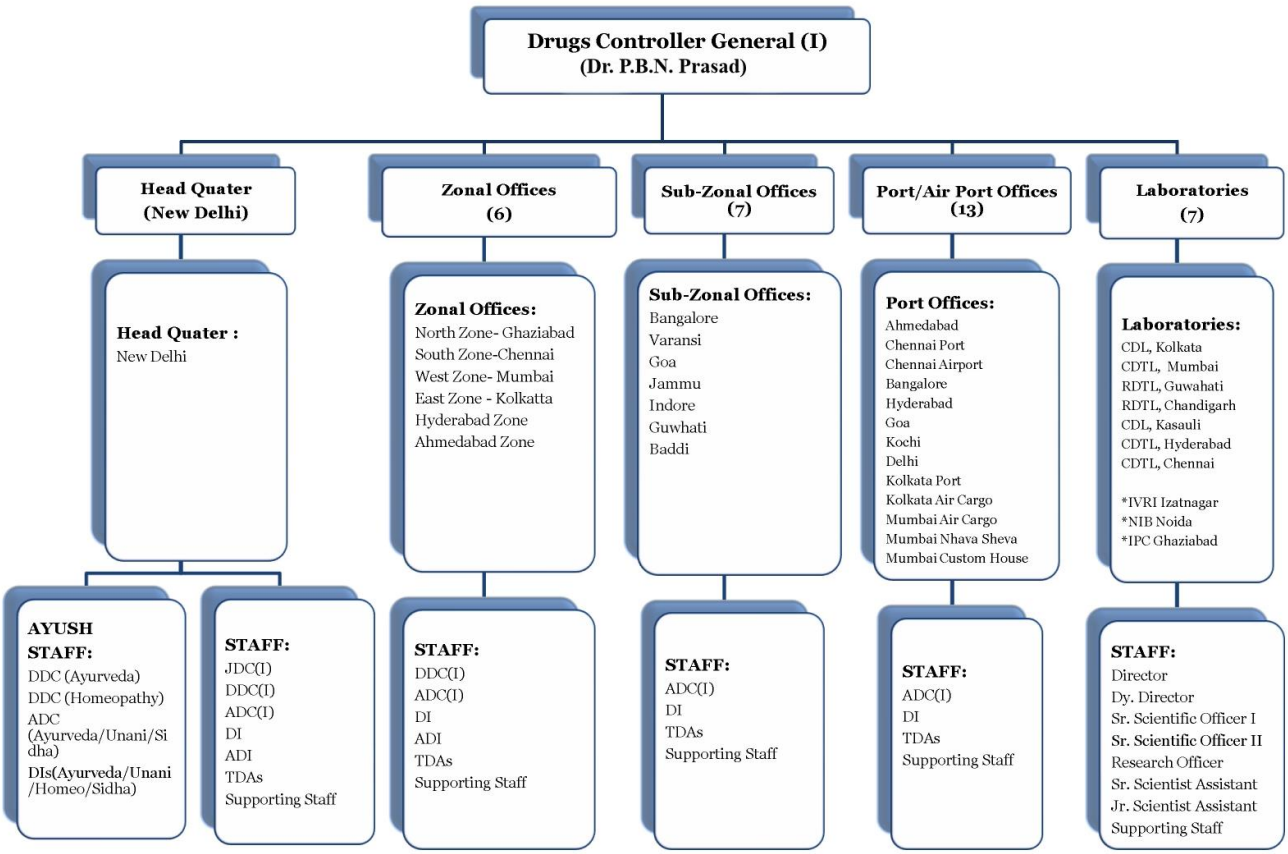
Central Drugs Standards Control Organization (CDSCO):

- 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.

Major functions of CDSCO:

Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters.

The organization chart:



Indian Pharmacopoeia Commission (IPC)

Introduction:

- 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.
- The standards that are in effect since 1 December 2010, are the Indian Pharmacopoeia 2010 (IP 2010).
- The Pharmacopoeia 2014 was released by Health Minister Ghulam Nabi Azad on 4 November 2013.

- The Pharmacopoeia 2018 was released by Secretary, Ministry of Health & Family Welfare, and Government of India.

Mission

- To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

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.

Objectives

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices and to keep them updated by revision on a regular basis.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations therefrom.
- To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms.
- To take note of the different levels of sophistication in analytical testing/ instrumentation available while framing the monographs.
- To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.
- To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards.
- To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgrading /revision.
- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles /materials.
- To publish the National Formulary of India for updating medical practitioners and other healthcare professionals.
- To act as a National Coordination Centre for Pharma-covigilance Programme of India.

Pharmacopoeia –

Introduction of Pharmacopoeia:

- Pharmacopoeia has been the authoritative organization working to ensure the consistency and quality of medicines.
  Pharmacopoeia is the formulation of drugs. It is the standard book for preparation of drugs.
  The book is published in a country under the authority of its own government.
  Pharmacopoeia is derived from Greek word

Pharmakon – Drugs
Copoeia – Means to make

Type of Pharmacopoeia / List of Pharmacopeia

- We cannot call it a specific type because every country has a own Pharmacopoeia.
- First of all, let's know about our Indian Pharmacopoeia. When did this book become public, Which edition of it is running now?
  - ✓ Indian Pharmacopoeia
  - ✓ British Pharmacopoeia
  - ✓ United States Pharmacopoeia

Indian Pharmacopoeia:

- The Indian Pharmacopoeia is published by the Indian Pharmacopoeia commission (IPC) on behalf of the ministry of health and family welfare Government of India.
- Bengal Pharmacopoeia 1844 – But this book was not made public, just this name was kept.
  Legal and official book published by IPC-1945.
- Indian Pharmacopoeia Headquarter – Ghaziabad (Uttar Pradesh)
  Indian Pharmacopoeia commission (IPC) regulated by Ministry Of Health And Family Welfare.
- Indian Pharmacopoeia is written in English and official title of monographs given in Latin.
- The Indian Pharmacopoeia is being processed to fulfill the requirement in the Drug And Cosmetics Act 1940 and rules 1945.
  In 1946 the government of India published the Indian Pharmacopoeia list which served as the suppliment to British Pharmacopoeia.
  After publication of list the government of India constituted a parmanent Indian Pharmacopoeia committee in 1948.

The following table describes the publication history of the Indian Pharmacopoeia.

Edition	Year	Volumes	Addendum/Supplement
1st Edition	**1955**	–	Supplement 1960
2nd Edition	**1966**	–	Supplement 1975
3rd Edition	**1985**	2	Addendum 1989
			Addendum 1991
4th Edition	**1996**	2	Addendum 2000
			Vet Supplement 2000
			Addendum 2002
			Addendum 2005
5th Edition	**2007**	3	Addendum 2008
6th Edition	**2010**	3	Addendum 2012
7th Edition	**2014**	4	Addendum 2015
			Addendum 2016
8th Edition	**2018**	4	Addendum 2019
			Addendum 2021

9th edition 2022

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