

**CENTRAL DRUG STANDARD  
CONTROL ORGANISATION  
(CDSCO)**

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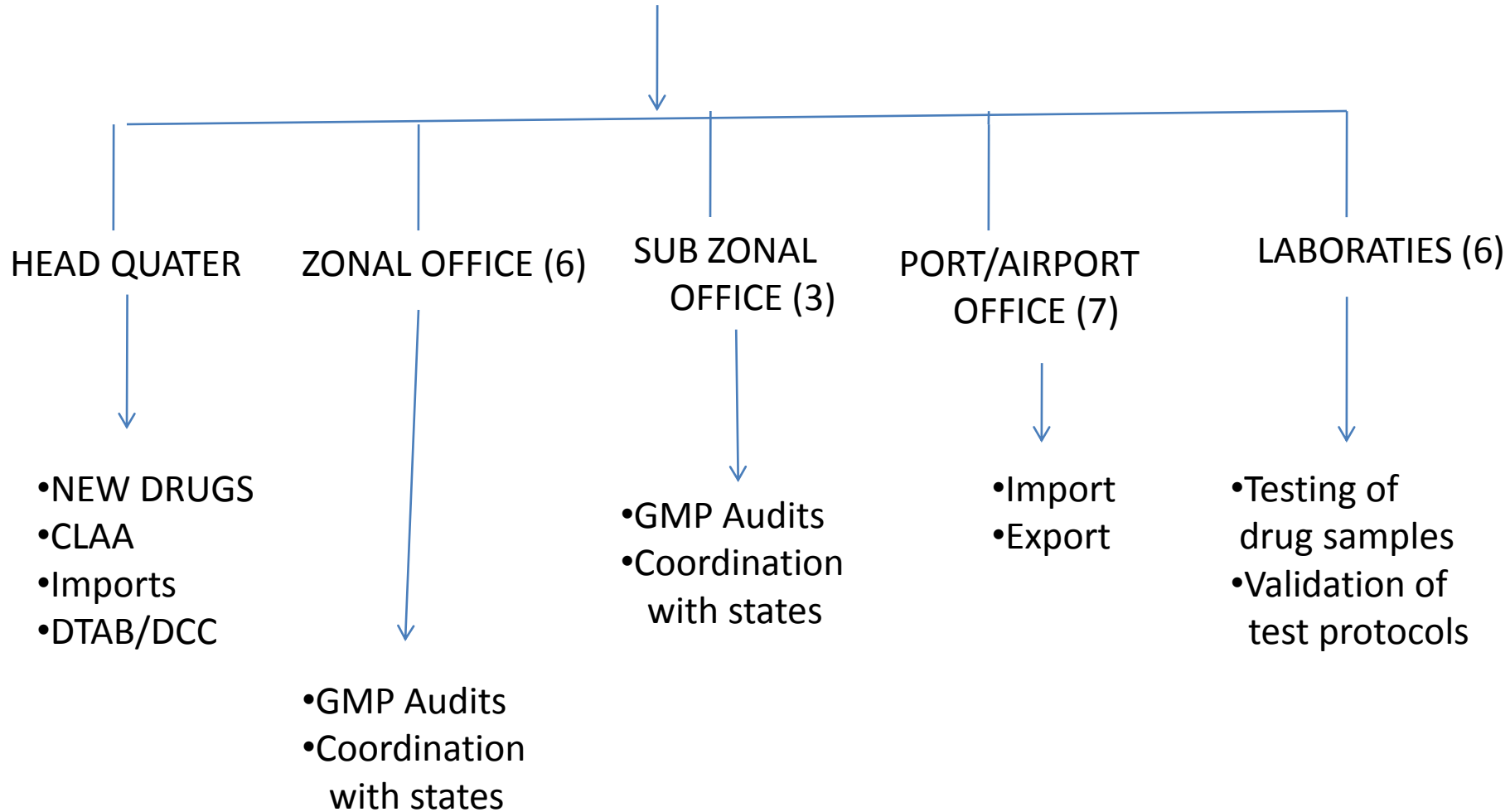
# INTRODUCTION

- The CDSCO of India is main regulatory body for regulation of pharmaceutical, medical devices and Clinical Trials.
- Head office of CDSCO is located in NEW DELHI and functioning under the control of Directorate General of Health Services, ministry of health and family welfare Government of India.

# Drugs Controller General of India [DCGI]

- He/she is a responsible for approval of New Drugs, Medical devices and Clinical Trails to be conducted in India.
- He is appointed by the central government under the DCGI the State drug control organization will be functioning.
- The DCGI is advised by the Drug Technical Advisory Board {DTAB} and the Drug Consultative Committed {DCC}.

# Organization Chart



# Zonal offices

- Mumbai
  - Kolkata
  - Chennai
  - Ghaziabad
  - Ahmedabad
  - Hyderabad
- ☐ These are involved in GMP audits and inspection of manufacturing units of large volume parental, sera, vaccine and blood products.

## ❑ Sub-zonal office:-

- I. Chandigarh
- II. Jammu
- III. Benglore

These centre co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement.

# Central Drugs Testing Laboratories

- Central Drug Laboratory, Kolkata
- Central Drug Testing Laboratory, Mumbai
- Central Drug Testing Laboratory, Chennai
- Central Drug Laboratory, Kasauli
- Regional Drug Testing Laboratory, Guwahati
- Regional Drug Testing Laboratory, Chandigarh

These laboratories are responsible for quality control of drugs and cosmetics in the country.

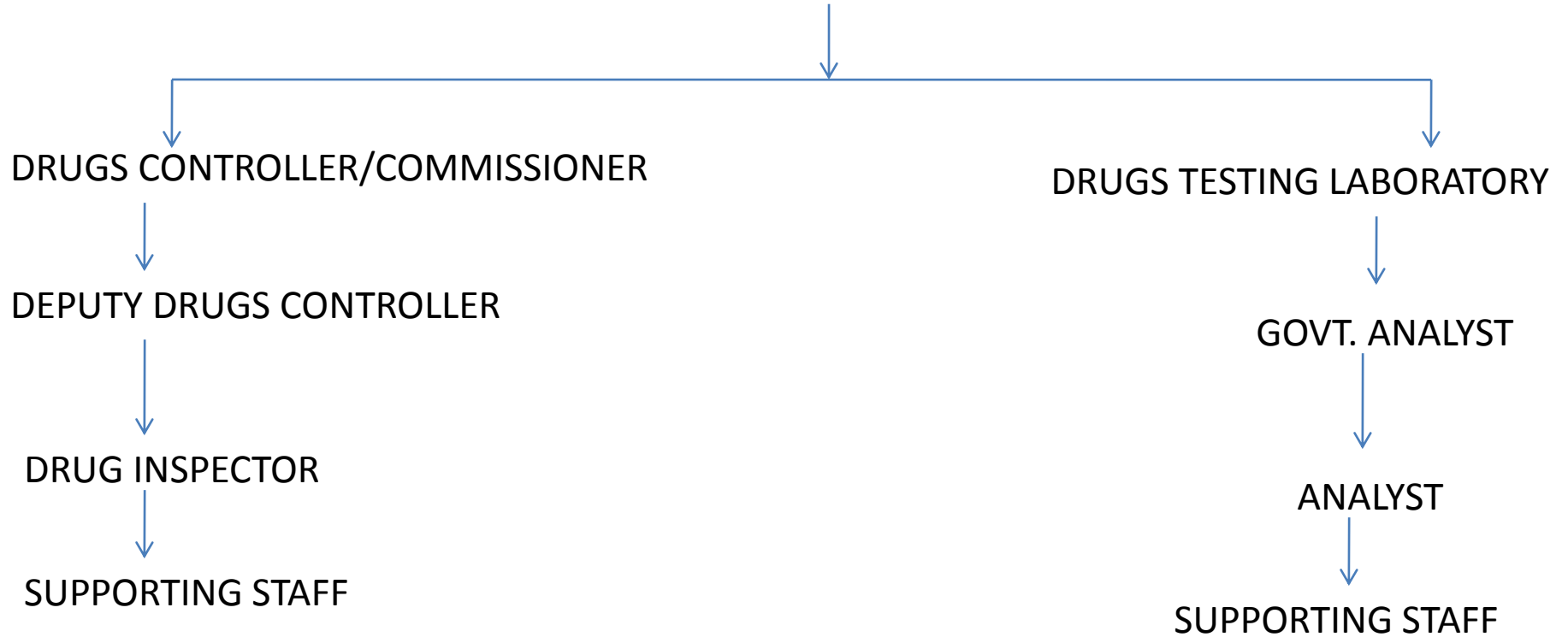
# Functions of CDSCO in Center

- Approval of new drugs and clinical trials.
- Import Registration and Licensing
- Licensing of Blood Banks, LVPs, Vaccines, r-DNA products and some Medical devices and Diagnostic agents.
- Amendment to D&C Act and Rules.
- Participation in WHO GMP certification schemes.

# Functions of CDSCO in Center

- Banning of drugs and cosmetics.
- Grant to test license, personal license, NOC's for export.
- Testing of drugs by Central Labs.
- Publication of Indian Pharmacopoeia.
- Monitoring adverse drug reactions.
- Guidance on Technical matters.

# STATE DRUGS CONTROL ORGINATION



# Function of State Licensing Authorities

- Licensing of drug testing laboratories.
- Approval of drug formulation for manufacture.
- Monitoring of quality of Drugs and cosmetics, manufactured by respective state and those marketed in the state.

# Function of State Licensing Authorities

- Investigation and prosecution in respect of contravention in respect of contravention of legal provisions.
- Administrative actions.
- Pre- and post- licensing inspection.
- Recall of sub-standard drugs.

# Approval For New Drugs

- New drugs are permitted to be marketed in country in accordance with the permission granted by DCGI after ensuring that these drugs are
  - Safe
  - Effective
  - Comply with requirement of schedule Y of the Drug and Cosmetic rules.

- Applicants are required to provide technical data in respect of safety and efficacy before these could be permitted to be marketed in country.
- Definition of new drug also includes fixed dose combination which are required to be marketed for the 1<sup>st</sup> time in country.

# Clinical Trials

- Schedule Y of drugs and cosmetics act explain the guideline for grant of permission for conducting clinical trials in India.
- The protocol for such trials are examined by the office of DCGI before the permission are granted.
- Office of DCGI also grants permission for conducting bioequivalence studies.

- a. Registration of clinical trials has been made mandatory with centralized clinical trial registry of ICMR with effect from 15<sup>th</sup> 2009.
- b. Drug and Cosmetic rules are being amended to make mandatory the registration of clinical research organizations.
- c. Drug and Cosmetic act is proposed to be amended to include a separate chapter on clinical trials.

# MEDICAL DEVICES

- Any instrument, apparatus, implement machine, appliance, implant, invitro reagent used for

**Thank you**