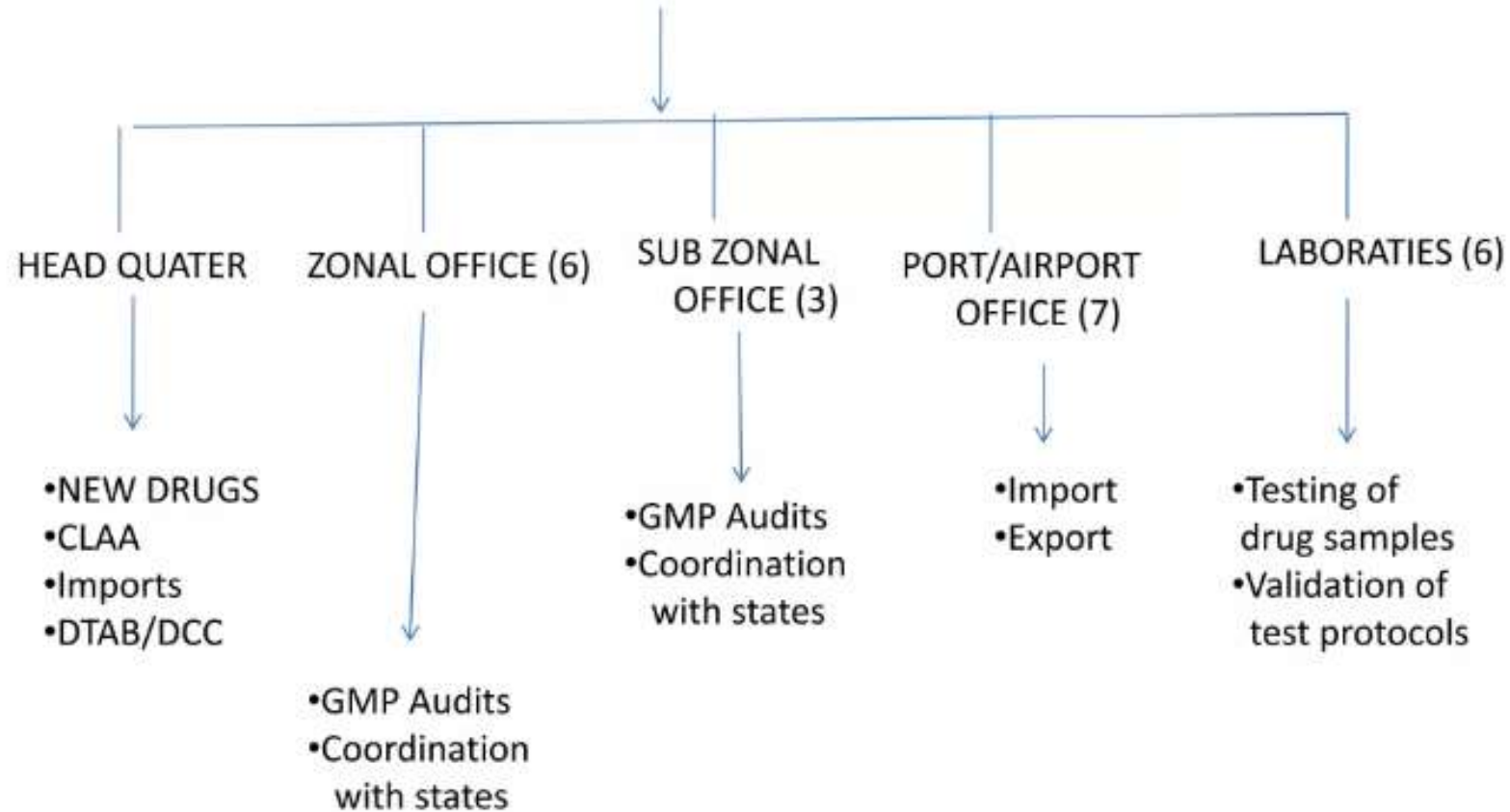


**CENTRAL DRUGS STANDARDS
CONTROL ORGANIZATION
(CDSCO)**

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.

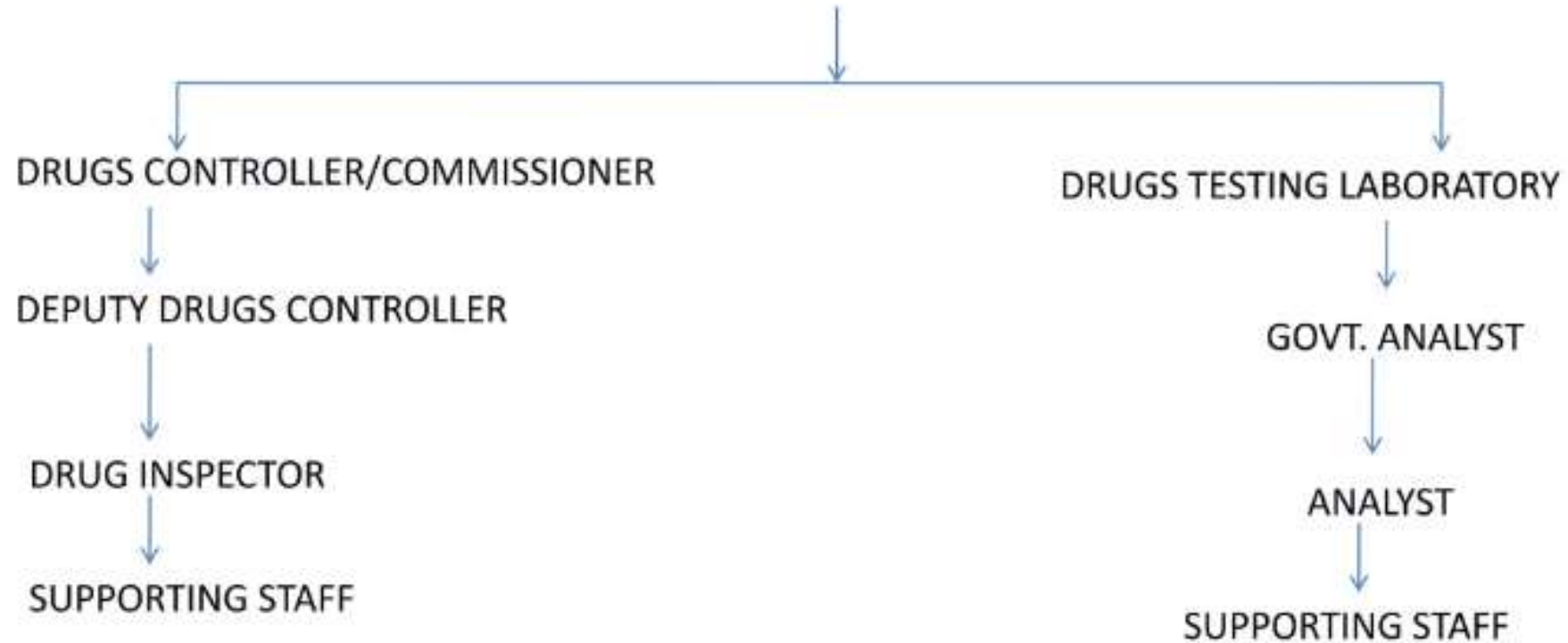
Organization Chart



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 1st time in country.

DRUG CONTROLLER GENERAL OF INDIA

- Within the CDSCO, the Drug Controller General Of India (DCGI), regulates pharmaceutical and medical devices, under the gamut of Ministry of Health and Family Welfare.
- He/She is responsible for approval of new drugs, medical devices, and Clinical Trial to be conducted in India
- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).
- **DCGI:** Dr. S. Eswara Reddy(1)

CLINICAL TRIAL PROCESS

- An application to conduct clinical trials in India should be submitted along with the data of chemistry, manufacturing, control and animal studies to DCGI.
- The data regarding the trial protocol, investigator's brochures, and informed consent documents should also be attached.
- A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only after approval of DCGI and ethical committee.
- To determine the maximum tolerated dose in humans, adverse reactions, etc. on healthy human volunteers, Phase I clinical trials are conducted. The therapeutic uses and effective dose ranges are determined in Phase II trials in 10-12 patients at each dose level. The confirmatory trials (Phase III) are conducted to generate data regarding the efficacy and safety of the drug in ~ 100 patients (in 3-4 centers) to confirm efficacy and safety claims. Phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers. (4)

- If the new drug substance is not marketed in any other country. The new drug registration (using form 44 along with full pre-clinical and clinical testing information) is applied after the completion of clinical trials.
- The comprehensive information on the marketing status of the drug in other countries is also required other than the information on safety and efficacy.
- The information regarding the prescription, samples and testing protocols, product monograph, labels, and cartons must also be submitted. The application can be reviewed in a range of about 12-18 months.
- After the NDA approval, when a company is allowed to distribute and market the product, it is considered to be in Phase IV trials, in which new uses or new populations, long-term effects, etc. are explored. (4)

COSMETICS & MEDICAL DEVICES APPROVAL

- For the import of cosmetics into India, the cosmetic products need to be registered with the licensing authority as defined under Rule 21 of Drugs & Cosmetic Rules.
- The regulatory application needs to be submitted in Form 42 along with Soft copies of the information about the brands, products and manufacturer, product specification and testing protocol to receive the cosmetics registration certificate in Form 43.
- The Cosmetics that are supposed to be imported are categorized into Brands. These brands are divided into 4 main category namely Skin products, Hair and scalp products, nail and cuticle products and Oral hygiene products.
- License will be granted within 6 months by CDSCO. However, as per a notification in 2014, the targeted timeline for cosmetics regulatory approval process is 90 days. (5)

RECENT ADVANCES IN CDSCO

- To improve ease of doing business, CDSCO increases the validity of the WHO GMP certificate to three years. Earlier it was valid for two years, said DCGI, Eswara Reddy during the 6th annual International Exhibition of Pharma and Healthcare.
- The protocol for clinical trial approvals has also been changed by setting the timeline of approval at 45 days. Once approval does not come within this timeline, the protocol would be deemed to be approved.
- 56th DCC held on 01st June 2019, DCC after deliberation opined that New Drugs and Clinical Trials Rules, 2019 for mandating inspections of BA/BE study centres by officers authorized by State Licensing Authorities.
- 82nd DTAB held on 02.04.2019, examine the Safety and Efficacy of unapproved FDCs which were licensed by State Licensing Authorities without due approval of DCG(I). (6)